No. ____ Supreme Court, U.S.
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Supreme Court of the United States

WARNER-LAMBERT COMPANY LLC and PFIZER INC.,

Petitioners,

—v.—

KIMBERLY KENT, ET AL.,

Respondents.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT

PETITION FOR A WRIT OF CERTIORARI

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ISSUES PRESENTED FOR REVIEW

1. Whether, under the conflict preemption principles in *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001), federal law preempts state law to the extent that it requires the fact-finder to determine whether the defendant committed fraud on a federal agency that impacted the agency's product approval, where the agency—which is authorized by Congress to investigate and determine fraud—has not found any such fraud, and thus—as in *Buckman*—the state requirement would interfere with the agency's critical functions.

2. Whether, under the conflict preemption principles in *Buckman*, federal law preempts the provision in a Michigan statute that allows a product liability claim to be maintained against a manufacturer of an FDA-approved drug where, without an FDA finding of fraud on that agency, the fact-finder is required to make a finding under state law as to whether the manufacturer committed fraud-on-the-FDA and whether, in the absence of that fraud, the FDA would not have approved the drug.

LIST OF PARTIES TO THE PROCEEDINGS

Petitioners Warner-Lambert Company LLC and Pfizer Inc. were defendants in the district court and appellees in the court of appeals.

Respondents are the following 29 individuals who were plaintiffs in the district court and appellants in the court of appeals:

Kimberly Kent, Personal Representative of the Estate of Virginia Kent

Emmett Kent

Elizabeth M. Graham

Robert C. Graham

Connie Armstrong

Lauranane Bradley

Raymond Bradley, Sr.

Glenn Chandler

Billie Jo Flynt

Shelly Grotenhius

Judy Ann Hearn

Colleen Rose Herndon

Michael Herndon

Michael H. Kanakry

Mary Ann Kanakry

Julia Lynne Martin

Royal M. Martin

Janice L. Kimmel, Personal Representative of the Estate of Thea Martz

Mona Lorene Przytulski

David A. Rice, Personal Representative of the Estate of Robert Rice

Anita Louise Schultz

Richard P. Schultz

James Soukup, Personal Representative of the Estate of Barbara Soukup

Jennifer St. Pierre, Personal Representative of the Estate of Raymond St. Pierre

Donald R. Waun

Jean Waun

Linda Sherman

Stanley Sherman

Nancy Fisher, Individually and as Personal Representative of the Estate of Troy Fisher

CORPORATE DISCLOSURE STATEMENT

Pursuant to Rule 29.6 of the Rules of the Court, Petitioners Warner-Lambert Company LLC and Pfizer Inc. state:

Warner-Lambert Company LLC is wholly owned by Pfizer Inc. Pfizer Inc. has no parent and no publicly held company owns more than 10% of its stock.

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Warner-Lambert Company LLC ("Warner-Lambert") and Pfizer Inc. ("Pfizer") petition for a writ of certiorari to review the judgment of the United States Court of Appeals for the Second Circuit entered in this case on January 18, 2007.

OPINIONS BELOW

The court of appeals' opinion (Appendix ("App.") 1a-28a) is reported at 467 F.3d 85. The district court's order is unreported. The district court's order and the transcript in which the district court set forth its reasons supporting the order are reprinted at App. 29a-38a.

JURISDICTION

The court of appeals entered judgment on January 18, 2007. On February 12, 2007, the court of appeals denied a timely petition for rehearing. App. 39a-40a. The jurisdiction of this Court is invoked under 28 U.S.C. § 1254(1).

CONSTITUTIONAL AND STATUTORY PROVISIONS INVOLVED

The basis for implied conflict preemption, which is at issue here, is the Supremacy Clause of the Constitution, which provides in relevant part: "[T]he laws of the United States . . . shall be the supreme Law of the Land . . . any Thing in the Constitution or Laws of any State to the Contrary notwithstanding." U.S. CONST. art. VI, cl. 2, reprinted at App. 41a.

The Second Circuit opinion below conflicts with a Sixth Circuit opinion in regard to preemption of a portion of a Michigan statute that makes proof of fraud-on-the-FDA a prerequisite to a product liability action.

The relevant sections of Michigan's product liability statute provide:

> In a product liability action against a manufacturer or seller, a product that is a drug is not defective or unreasonably dangerous, and the manufacturer or seller is not liable, if the drug was approved for safety and efficacy by the [FDA], and the drug and its labeling were in compliance with the [FDA's] approval at the time the drug left the control of the manufacturer or seller.

MICH. COMP. LAWS § 600.2946(5), reprinted at App. 42a. An exception provides for manufacturer liability, if the manufacturer

> [i]ntentionally withholds from or misrepresents to the [FDA] information concerning the drug that is required to be submitted under the federal food, drug, and cosmetic act . . . and the drug would not have been approved, or the [FDA] would have withdrawn approval for the drug if the information were accurately submitted.

MICH. COMP. LAWS § 600.2946(5)(a), reprinted at App. 42a.

The relevant provisions of the Federal, Food, Drug, and Cosmetic Act ("FDCA") and related regulations are reprinted at App. 43a-192a and cited in *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001), where the Court held that state-law claims based on fraud-on-the-FDA conflict with FDCA provisions and therefore are impliedly preempted.

The pertinent statutory and regulatory provisions are as follows: FDA has a duty to ensure that "drugs are safe and effective" for their intended uses. 21 U.S.C. § 393(b)(2)(B). FDA regulates each step of the clinical

investigation process that precedes approval. *See generally* 21 U.S.C. § 355; 21 C.F.R. Parts 312, 314. A pharmaceutical company must submit a large volume of information for its "new drug application" ("NDA"). 21 U.S.C. § 355(b); 21 C.F.R. § 314.50. In reviewing clinical and scientific research to assess safety and effectiveness, "FDA is required to exercise its scientific judgment to determine the kind and quantity of data and information an applicant is required to provide for a particular drug to meet the statutory standards." 21 C.F.R. § 314.105(c). After approval, holders of NDAs are responsible for further reporting, 21 U.S.C. § 355(k), 21 C.F.R. §§ 314.80, 314.81, which the FDA reviews to decide whether to continue approval, 21 U.S.C.§ 355(e), 21 C.F.R. § 314.150.

The federally mandated NDA process requires continual interaction between the FDA and the applicant about all aspects of the clinical trial program and the NDA. *See* 21 U.S.C. § 355; 21 C.F.R. Parts 312, 314; *see also* "The FDA's Drug Review Process: Ensuring Drugs Are Safe and Effective," FDA Consumer Magazine (July-August 2002), Pub No. FDA05 3242, as revised September 2005, available at http://www.fda.gov/fdac/features/2002/402_drug.html.

FDA has the power to conduct examinations and investigations concerning prescription drugs, 21 U.S.C. § 372, and the United States may enforce FDA's mandate by seeking injunctive relief, seizure of misbranded drugs, or criminal and civil penalties. 21 U.S.C. §§ 332-334.

FDA is empowered to investigate and punish fraud under 21 U.S.C. § 372. Citizens may report wrongdoing to the FDA and petition the agency to take action under 21 C.F.R. § 10.30. The FDA may pursue a wrongdoer under criminal statutes that proscribe false statements to

the federal government. *Buckman*, 531 U.S. at 349 (citing 18 U.S.C. § 1001). The agency also has authority to address fraud by seeking injunctive relief and civil penalties. 21 U.S.C. §§ 332, 333; *see also* 21 U.S.C. § 355(e)(5) (allowing FDA to withdraw drug approval where application contains any untrue statement of a material fact). FDA has established an enforcement policy concerning fraud in pre-market submissions that sets forth the remedies it may pursue. *See* Fraud, Untrue Statements of Material Facts, Bribery, and Illegal Gratuities; Final Policy, 56 Fed. Reg. 46,191, 46,199-200 (Sept. 10, 1991); *see also* FDA Compliance Policy Guide § 120.100, "Fraud, Untrue Statements of Material Facts, Bribery, and Illegal Gratuities," issued July 1, 1991 (announced in 55 Fed. Reg. 52,323 (Dec. 21, 1990)), available at http://www.fda.gov/ora/compliance_ref/cpg/cpggenl/cpg120-100.html. All lawsuits to enforce the FDCA's provisions "shall be by and in the name of the United States." 21 U.S.C. § 337(a).

STATEMENT OF THE CASE

The basis for federal jurisdiction in the district court is diversity. 28 U.S.C. § 1332. Respondents (hereinafter "Plaintiffs") are Michigan citizens, who are plaintiffs in product liability actions filed in Michigan state court against Petitioners Warner-Lambert and Pfizer (collectively "Warner-Lambert")[1], claiming injuries from a prescription drug, Rezulin, approved by FDA for treatment of diabetes. Warner-Lambert removed those actions to federal district court in Michigan. The Judicial Panel on Multidistrict Litigation established the Rezulin Multidistrict Litigation ("Rezulin MDL") pursuant to

[1] Warner-Lambert manufactured Rezulin while it was marketed from March 1997 to March 2000. Pfizer acquired Warner-Lambert in June 2000.

28 U.S.C. § 1407, and transferred these cases and others to the Rezulin MDL court in the Southern District of New York.[2]

In their state law product liability claims under the Michigan statute quoted above, several of the Plaintiffs allege that Warner-Lambert

> "knowingly concealed material facts about the safety and efficacy of Rezulin from the FDA, which would have prevented its approval and/or resulted in its earlier removal from the market." App. 337a, 344a, 354a.

The FDA approved Rezulin as safe and effective for use consistent with its labeling at all times while it was marketed. After FDA approved Rezulin for sale in March 1997, the FDA continually scrutinized the drug and its warning labels and maintained its approval status at all times until Warner-Lambert withdrew Rezulin in March 2000. Warner-Lambert withdrew the drug at FDA's suggestion because of adverse side effects and the advent of two new similar drugs in the same class that rendered Rezulin outmoded.[3] A number of physicians

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[2] The five cases at issue in this appeal were transferred to the Rezulin MDL. *In re Rezulin Prods. Liab. Litig*, Docket No. 1348, CTO-1 (J.P.M.L. June 21, 2000) (*Kent*); *In re Rezulin Prods. Liab. Litig*, Docket No. 1348, CTO-7 (J.P.M.L. Dec. 12, 2000) (*Graham*). *In re Rezulin Prods. Liab. Litig*, Docket No. 1348, CTO-34 (J.P.M.L. October 11, 2001) (*Armstrong*); *In re Rezulin Prods. Liab. Litig*, Docket No. 1348, CTO-56 (J.P.M.L. April 23, 2003) (*Sherman*); *In re Rezulin Prods. Liab. Litig*, Docket No. 1348, CTO-69 (J.P.M.L. Apr. 23, 2004) (*Fisher*).

[3] *See* App. 7a; Center for Drug Evaluation and Research, Food and Drug Administration, Endocrinologic and Metabolic Drugs Advisory Committee Meeting Transcript ("EMDAC") at 82 (May 19, 2000), available at http://www.fda.gov/ohrms/dockets/ac/00/transcripts/3615t1.pdf.

and patients sought to keep the drug on the market because of its therapeutic benefits in treating diabetes.[4]

Warner-Lambert moved for judgment on the pleadings on the ground that Plaintiffs could not establish, under the Michigan product liability statute, that Rezulin—as an FDA-approved drug—was "defective." Warner-Lambert further argued that a portion of the Michigan statute—which required plaintiffs to obtain a state law finding that Warner-Lambert had engaged in fraud-on-the-FDA without which the FDA would not have approved Rezulin—was impliedly preempted under *Buckman*. The motion relied on *Buckman's* holding that "state-law fraud-on-the-FDA claims conflict with, and are therefore impliedly preempted by, federal law." 531 U.S. at 348. The motion also relied on *Garcia v. Wyeth-Ayerst Labs.*, 385 F.3d 961 (6th Cir. 2004), which applied *Buckman* to preempt the portion of the Michigan statute requiring a state law finding of fraud-on-the-FDA (where the FDA had not itself found fraud). *Garcia* also held that the remainder of the statute, which provided that FDA-approved drugs are not *defective* for purposes of Michigan products liability law, should be severed and enforced independently.

The district court granted Warner-Lambert's motion for judgment on the pleadings, relying on *Garcia* and its application of *Buckman*. App. 29a-38a. The district court reasoned that "[i]f plaintiffs covered by the Michigan statute were able to litigate claims of fraud on the FDA in individual personal injury suits, whether in state courts or in federal courts, the potential would exist for the FDA's personnel to be drawn into those controversies on a case-by-case basis over and over again," resulting in "enormous" "interference with the proper discharge of

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[4] EMDAC, n. 3, *supra*, at 13-14, 17-27.

the mission that Congress created the FDA to perform." App. 35a-36a.

In direct conflict with *Garcia*, the Second Circuit reversed the district court decision. App. 1a-28a. The court relied on a presumption against preemption, citing *Medtronic Inc. v. Lohr*, 518 U.S. 470 (1996), even though *Buckman* had explicitly rejected that presumption for state law claims of fraud-on-the-FDA. The Second Circuit read *Buckman* narrowly so that it applied only to claims based "solely" on fraud-on-the-FDA, which in its view did not include claims requiring plaintiffs to prove the exception in the Michigan statute. The court of appeals also was dismissive of *Buckman's* concerns with the adverse impact that state law determinations of fraud-on-the-FDA could have on the FDA's internal operations and the regulatory process.

REASONS FOR GRANTING THE PETITION

The Second Circuit decision threatens to upset the basic understanding of preemption law that has informed this Court's decisions since *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218 (1947), cited in *Buckman*, 531 U.S. at 347. As *Buckman* held, under this line of decisions there is no presumption against preemption of state law with respect to an issue that is not historically within a field occupied by the states, such as finding fraud on a federal agency that affected the agency's decision-making. *Id.* at 348. *Buckman* found that the FDA approval process was a "comprehensive scheme." The Court concluded that "[s]tate law fraud-on-the-FDA claims inevitably conflict with the FDA's responsibility to police fraud consistently with the Administration's judgment and objectives," and would "cause applicants to fear that their disclosures to the FDA, although deemed

appropriate by the Administration, will later be judged insufficient in state court." *Id.* at 348, 350, 351.

The circuit courts are sharply split in their application of *Buckman* and the preemption doctrine. The Second Circuit here confined *Buckman* to the narrow circumstance where a plaintiff has asserted a stand-alone cause of action for "fraud-on-the-FDA"—in essence a claim that is pleaded entirely on that theory. App. 19a-23a. A number of district courts as well as a state court have adopted a similarly narrow approach. *See, e.g., Ackermann v. Wyeth Pharmaceuticals*, No. 4:05CV84, 2006 WL 354492, at *8 (E.D. Tex. Dec. 7, 2006); *In re: St. Jude Medical, Inc. Silzone Heart Valves Prods. Liab. Litig.*, No. MDL 01-1396, 2004 WL 45503, at *13 (D. Minn. Jan. 5, 2004); *Bryant v. Hoffman-LaRoche, Inc.*, 585 S.E.2d 723, 725 (Ga. Ct. App. 2003).[5]

The Sixth Circuit and Ninth Circuits, as well as the Third Circuit prior to *Buckman*, have taken a more functional approach—applying *Buckman* to preempt state law to the extent that it requires a plaintiff to establish a fraud on a federal agency, regardless of the technical nature of the pleading in which that requirement arises. This line of cases has looked to whether the state-law requirement—that the fact-finder make a determination as to whether a federal agency has been defrauded—would lead to the same impositions on the federal agency that concerned this Court in *Buckman*. As shown above, the Sixth Circuit's preemption decision in *Garcia* squarely conflicts with the Second Circuit decision here on this issue. Taking an approach like that of the Sixth Circuit, the Ninth Circuit has held that under "[t]he rationale articulated by the Supreme Court in *Buckman*,"

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[5] All unpublished decisions cited herein are reprinted at App. 193a-331a.

plaintiff's claim for tortious interference with prospective business advantage was preempted where plaintiff would have to prove that defendant committed a fraud on the Environmental Protection Agency to prevail. *Nathan Kimmel, Inc. v. DowElanco*, 275 F.3d 1199, 1205-06 (9th Cir. 2001). The Third Circuit, in a decision that presaged *Buckman*, held that "[i]f a medical device manufacturer's claim that the MDA pre-empts a plaintiff's cause of action depends in the first instance upon proof that its Premarket Approval was not fraudulently obtained, courts would have to engage in the intrusive inquiry which we have demonstrated is forbidden." *Michael v. Shiley, Inc.*, 46 F.3d 1316, 1329 (3d Cir. 1995).

Federal district courts and state courts have rendered holdings consistent with the Sixth, Ninth and Third Circuits' approach, and contrary to the Second Circuit's narrow view of *Buckman*. *See Webster v. Pacesetter*, 259 F. Supp. 2d 27, 36 (D.D.C. 2003) (plaintiffs precluded by *Buckman* from "arguing" that defendants failed to comply with FDA regulations in regard to design and labeling of medical device, where their claim was denominated as for common law failure to warn); *Healthpoint, Ltd. v. Ethex Corp.*, 273 F. Supp. 2d 817, 851 (W.D. Tex. 2001) (dismissed unclean hands defense to trademark infringement suit premised on alleged misbranding under the FDCA on ground that, citing *Buckman*, the defense as pleaded would have "require[d] interpretation and application of FDA regulations," which was better left to FDA to determine); *Baker v. St. Jude Medical, S.C., Inc.*, 178 S.W.3d 127, 138 (Tex. Ct. App. 2005) (common law fraud claims preempted where plaintiffs alleged that "St. Jude withheld, or unreasonably delayed, in providing the FDA with information that it had regarding adverse effects associated with Silzone heart valve"); *Ledbetter v. Merck & Co., Inc.*, No.

2005-59499, slip op. at 8 (Tex. Dist. Ct. Harris County Apr. 20, 2007) (held that federal law preempted portion of state statute that required that "in order to pursue a failure to warn case, plaintiffs must prove that required and material information was withheld from the FDA," and concluded that "[w]hether it is an element of plaintiffs' cause of action, or a way to defeat an affirmative defense, the proof is the same").

The issue presented in this case is a specific manifestation of the split in the circuits and lower courts described above—whether federal law preempts the portion of a state statute that requires a fact-finder to make a determination concerning alleged fraud-on-the-FDA, absent a determination by the FDA on that issue. In *Garcia,* the Sixth Circuit had held that implied conflict preemption applied to the portion of the Michigan statute that authorized finders of fact to decide under state law—as a prerequisite to product liability claims—whether there was material fraud-on-the-FDA, unless the FDA itself had made such a finding. *Garcia* recognized that the powerful concerns expressed in *Buckman* were sparked by the intrusion of such a state law requirement on the FDA's regulatory process. Moreover, the Sixth Circuit held that those concerns are equally relevant whether they are raised in a state common law action for fraud-on-the-FDA or under a statutory exception to a provision that treats FDA drug approval as dispositive of product liability claims.

The Second Circuit took precisely the opposite position when it exalted form over substance to rule that the concerns expressed in *Buckman* somehow vanish because of the difference in the procedural posture in which a court under state law would be required to determine if there was material fraud-on-the-FDA. As a result, the Second Circuit adopted an unduly narrow reading of *Buckman* as

applying only to stand-alone claims that are in effect denominated as for fraud-on-the-FDA. In so ruling, the Second Circuit misread *Medtronic* and jettisoned a half century of preemption law culminating with *Buckman*. Indeed, the decision of the Second Circuit below is the most limited interpretation of *Buckman* to date and most egregiously ignores *Buckman*'s rationale.

Moreover, the Second Circuit's holding will interfere with the FDA's ability to perform its critical functions, which is precisely what this Court sought to avoid in *Buckman*. 531 U.S. at 349-51. Findings of fraud-on-the-FDA would inevitably disrupt the regulatory process by encouraging manufacturers to supply unnecessary information to the FDA for fear that the failure to do so will lead to state-law liability; by discouraging manufacturers from seeking approval for beneficial drugs that are not risk-free; by distorting the FDA's decision-making process to anticipate potential state-law review of that process; and by burdening FDA personnel who are ordered to testify as witnesses in state-law products liability cases concerning the FDA's decision-making process.

An additional reason for granting certiorari in this case is that the issues reach beyond the Michigan statute on which the Sixth and Second Circuit are in conflict. As part of tort reform efforts throughout the country, other states have enacted statutes limiting claims or damage recoveries for FDA-approved drugs unless the finder of fact determines under state law that there was fraud-on-the-FDA. Thus, Texas has enacted legislation, which—similar to the Michigan statute—provides for a presumption that FDA-approved warnings on pharmaceutical products are adequate, which can be rebutted if the plaintiff establishes fraud-on-the-FDA. *See* TEX. CIV. PRAC. & REM. CODE § 82.007. In addition, six states have a fraud-on-the-FDA exception to a rule bar-

ring punitive damages for FDA-approved drugs. *See* ARIZ. REV. STAT. § 12-701; N.J. STAT. ANN. § 2A:58C-5(c); N.D. CENT. CODE § 32-03.2-11(6), (7)(a); OHIO REV. CODE ANN. § 2307.80(C); OR. REV. STAT. ANN. § 30.927; UTAH CODE ANN. § 78-18-2. All of these statutes reflect a trend to limit state law product liability claims or recoveries where products have been approved and are regulated by the federal government.[6] Thus, the issue raised by this petition has a broad impact on other statutes. A Michigan appellate court, a Texas state court and federal district courts in Tennessee, Pennsylvania and Arizona have followed the Sixth Circuit decision in finding preemption of such state law requirements, while a district court in Texas adopted the formalistic approach of the Second Circuit here.[7] *See* discussion of *Garcia* in Point I, *infra*.

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[6] David G. Owen, *Special Defenses in Modern Products Liability Law*, 70 MO. L. REV. 1, 20 22 (2005).

[7] *See Duronio v. Merck & Co., Inc.*, No. 267003, 2006 WL 1628516, at *5 (Mich. Ct. App. June 13, 2006) (agreeing with the Sixth Circuit's decision in *Garcia* that the fraud on the FDA exception in MICH. COMP. LAWS § 600.2946(5)(a) is partially preempted by federal law); *Ledbetter v. Merck & Co., Inc.*, No. 2005-59499, slip op. at 9 (Tex. Dist. Ct. Harris County Apr. 20, 2007) (following *Garcia* and holding that the fraud on the FDA exception under Tex. Civ. Prac. & Rem. Code § 82.007 is preempted except where FDA has "made a determination that material and relevant information was either withheld or misrepresented concerning Vioxx"). *In re Aredia and Zometa Prods. Liab. Litig.*, No. 3:06-MD-1760, 2007 WL 649266, *8, *9 n.17 (M.D. Tenn. Feb. 27, 2007) (New Jersey statute that "immunizes drug manufacturers from punitive damage liability *unless* the plaintiff can prove fraud on the FDA" is impliedly preempted unless the FDA itself finds fraud) (emphasis in original); *Henderson v. Merck & Co., Inc.*, No. 04-CV-05987-LDD, 2005 WL 2600220, *11 (E.D. Pa. Oct. 11, 2005) (following the "holdings of *Buckman* and *Garcia* and find[ing] that [the exceptions for fraud-on-the-FDA in the Michigan statute] are preempted by the FDCA in most situations"); *Kobar v. Novartis Corporation*, 378 F. Supp. 2d 1166, 1173 (D. Ariz. 2005) (both fraud on

State legislatures need direction from this Court on how they should conform their existing statutes or new legislation to federal preemption standards. The lower courts likewise need instruction on these preemption issues as they relate to the overlap between *Buckman* and *Medtronic*. Only this Court can provide the necessary guidance in this important area of federal constitutional law.

I. THE SECOND CIRCUIT'S DECISION BELOW IS IN CONFLICT WITH THE SIXTH CIRCUIT, AND WITH THE RATIONALE OF THIS COURT IN *BUCKMAN*, AS WELL AS THE THIRD AND NINTH CIRCUITS IN ANALAGOUS CASES, AS TO WHEN A STATE LAW REQUIREMENT OF A FINDING OF FRAUD ON A FEDERAL AGENCY IS IMPLIEDLY PREEMPTED.

Buckman—In *Buckman*, this Court held that "state-law fraud-on-the-FDA claims conflict with, and are therefore impliedly preempted by, federal law." 531 U.S. at 348. *Buckman* is one of a series of decisions in which the Court has charted a course between federal preemption and proper state authority. Thus, *Buckman* began its analysis by explaining that "[p]olicing fraud against federal agencies is hardly 'a field which the states have traditionally occupied . . . .' " *Id.* at 348 (citing *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947)). In *Rice*, the Court applied an "assumption" against superseding state powers because states had for

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the-FDA claim and statute requiring plaintiff to prove fraud to avoid punitive damages "place state courts, as finders of fact," in the position of deciding what role the withheld information would have had in the "FDA's complicated approval process."). *But see Ackermann v. Wyeth Pharmaceuticals*, No. 4:05CV84, 2006 WL 354492, at *8 (E.D. Tex. Dec. 7, 2006) (plaintiff's evidence of fraud on the-FDA rebuts presumption of no liability and does not in itself establish liability).

years regulated warehouses while the federal government had only recently decided to regulate them under a new statute. *Rice*, 331 U.S. at 330. The Court there found that comprehensive federal regulation overcame the "assumption." *Id.* at 236. In contrast, where the interests at stake are "uniquely federal" in nature, the conflict with the state need not be "as sharp" because of a concern that "the application of state law would 'frustrate specific objectives' of federal legislation." *Boyle v. United Technologies Corp.*, 487 U.S. 500, 504, 507 (1988) (finding preemption of common law design defect claim involving military equipment where federal law only authorized such a claim on a limited basis), cited in *Buckman*, 531 U.S. at 347.

Applying these well-established principles, this Court in *Buckman* explained that no presumption against preemption applies where "the relationship between a federal agency and the entity it regulates is inherently federal in character . . . ." 531 U.S. at 347. As the Court further explained, permitting fraud-on-the-FDA determinations under state law would frustrate the "flexibility [that] is a critical component of the statutory and regulatory framework under which the FDA pursues difficult (and often competing) objectives." *Id.* at 349. In addition, it would "inevitably conflict with the FDA's responsibility to police fraud consistently with the [FDA's] judgment and objectives." *Id.* at 350. Furthermore, allowing fraud-on-the-FDA claims would "dramatically increase the burdens facing potential applicants" in a manner "not contemplated by Congress," and create an "incentive" for manufacturers "to submit a deluge of information that the [FDA] neither wants nor needs" for "fear that their disclosures to the FDA, although deemed appropriate by the [FDA], will later be judged insufficient in state court." *Id.* at 350-51.

The same rationale precludes application of the Michigan statute (and similar state statutes) to the extent that those statutes require plaintiffs to prove fraud-on-the-FDA as a condition of recovery under state law. As with the Medical Device Amendments to the FDCA at issue in *Buckman*, the FDCA "sets forth a comprehensive scheme" for determining if an applicant is entitled to new drug approval. *Buckman*, 531 U.S. at 348. Therefore, as in *Buckman*, petitioner's dealings with FDA and the "very subject matter of petitioner's statements" to FDA were "dictated by that statute's provisions," and the relationship between petitioner and the FDA is inherently federal in character. *Id.* at 347-48. Thus, as in *Buckman*, no presumption against preemption applies.

Moreover, the FDCA, regulatory and other statutory provisions—described in *Buckman* as "aimed at detecting, deterring, and punishing false statements" during the approval process—are equally relevant here. *Id.* at 349. As described in *Buckman*, "citizens may report wrongdoing and petition the agency to take action." *Id.* (citing 21 C.F.R. § 10.30). The FDA and the federal government make extensive use of the provisions cited in *Buckman*, 531 U.S. at 349, to investigate and sanction fraud-on-the-FDA.[8] In the interactive drug regulatory

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[8] *See e.g., U.S. v. Barile*, 286 F.3d 749 (4th Cir. 2002) (criminal prosecution for false statements to FDA); *U.S. v. Prigmore*, 243 F.3d 1 (1st Cir. 2001) (prosecution for conspiring to defraud FDA); *U.S. v. Leichter*, 96 F. Supp. 2d 5 (D. Mass. 2000) (conspiracy to defraud FDA); FDA News P03 92, *Louisiana Ophthalmologist Fined $1.1 Million by FDA For Clinical Study Violations* (Nov. 5, 2003), available at http://www.fda.gov/bbs/topics/NEWS/2003/NEW00972.html; Michelle Meadows, *Company Gets a Guilty Reading in Glucose Monitor Case*, FDA CONSUMER MAGAZINE (March April 2001), available at http://www.fda.gov/fdac/departs/2001/201_irs.html (pharmaceutical manufacturer pleaded guilty to misdemeanor charges and agreed to pay $60 million in criminal and civil fines for *inter alia*, filing false or misleading information).

process, as in *Buckman*, "flexibility" is a "critical component of the framework under which the FDA pursues difficult (and often competing) objectives." *Id.* at 349. Superimposing state law determinations of any sort on top of "the FDA's detailed regulatory regime. . . will dramatically increase the burdens facing potential applicants—burdens not contemplated by Congress in enacting the FDCA . . . ." *Id.* at 350. Such burdens could discourage applicants from filing for approval of beneficial drugs that are not risk-free, and cause applicants to submit a deluge of information not wanted by FDA to assure that their submissions will not "later be judged insufficient in state court." *Id.* at 351. Plainly, these concerns arise under any state law that makes a finding of fraud-on-the-FDA a prerequisite to establishing liability under the state's tort law, when the FDA is empowered to make its own potentially inconsistent findings in regard to any such alleged fraud. Whether the requirement of a finding of fraud-on-the-FDA is called an "element" of the state-law claim or a "threshold prerequisite" is irrelevant to the vital institutional concerns expressed in *Buckman*.

The concurring opinion in *Buckman* suggested, as an accommodation between state and federal interests, that the conflict between the FDCA regulatory scheme and state tort fraud actions vanishes if the FDA has exercised its statutory power to find that fraud by an applicant induced it to approve a drug. As Justice Stevens stated, if "the FDA had determined that petitioner had committed fraud," plaintiffs' "state law fraud claim would not depend upon speculation as to the FDA's behavior in a counterfactual situation but would be grounded in the agency's explicit actions," and would not lead to "second-guessing the FDA's decision making or overburdening its personnel." 531 U.S. at 354. Once the FDA decides that there has been fraud, the burdens on the

administrative process and perverse incentives to drug applicants no longer pertain. This same accommodation was adopted by *Garcia* and ignored by the Second Circuit. It is as valid for the Michigan statutory exception's requirement as it was for the common law fraud-on-the-FDA claims in *Buckman*. In both procedural settings, "an essential link in the chain of causation that respondent must prove in order to prevail is that, but for petitioner's fraud, the allegedly defective [medical product] would not have reached the market." 531 U.S. at 353.

The Sixth Circuit decision in Garcia—Garcia applied *Buckman* to find partial preemption of what in reality is a statutory fraud-on-the-FDA claim, stemming from the exception in the Michigan statute that allows a product liability claim only where the fact-finder concludes that the defendant made intentional misrepresentations to FDA without which FDA would not have approved the medication. 385 F.3d 961. The "Michigan legislature has provided a general immunity for drug manufacturers with a specific exception for circumstances involving, *inter alia*, fraud on the FDA rather than a specific cause of action for fraud on the FDA. This difference, however, is immaterial in light of *Buckman*." *Id.* at 965-66 (footnote omitted). In both instances, "a plaintiff asks a state court to find bribery or fraud on the FDA." *Id.* at 967. Under the statute, a plaintiff must establish the exceptions to the immunity in the statute for FDA approved drugs "on the basis of *state court* findings of fraud on the FDA." *Id.* at 966 (emphasis in original). The Sixth Circuit concluded: "Such a state court proceeding would raise the same inter-branch-meddling concerns that animated *Buckman*." *Id.* at 966. For Plaintiff's here, as in *Buckman*, "the existence of these federal enactments is a critical element in their case." 531 U.S. at 353. Accordingly, *Buckman's* conclusion is fully applicable in the circumstances here, *i.e.*, that "this sort

of litigation would exert an extraneous pull on the scheme established by Congress, and it is therefore preempted by that scheme." *Id.*

The Sixth Circuit was careful to avoid reading *Buckman* too broadly, for it recognized that "the same concerns do not arise when the *FDA itself* determines that a fraud has been committed on the agency during the regulatory-approval process" and, therefore, in that circumstance, the Michigan statutory exception is not impliedly preempted. *Garcia*, 385 F.3d at 966 (emphasis in original). At bottom, the FDA is the appropriate forum for deciding, through its mandated procedures, whether it was deceived by a fraud by the applicant. Because a potential plaintiff may seek an FDA finding of fraud that has materially affected its decision-making, the partial preemption found by the Sixth Circuit does no more than recognize the FDA's primary jurisdiction over a claim of fraud on the agency. *See* 21 C.F.R. § 10.25(b) ("FDA has primary jurisdiction to make the initial determination on issues within its statutory mandate . . . .").

Plaintiffs in *Garcia* had offered no proof of fraud. They did not seek to satisfy the statutory exception but rather to use *Buckman* to persuade the court to overturn the entire immunity provision including the exception. Instead, the Sixth Circuit held that under Michigan law, while the exception was partially preempted, the statutory immunity for FDA-approved drugs should be preserved. *Garcia*, 385 F.3d at 967. As the court explained, "the Michigan legislature would have preferred the situation where drug manufacturers would enjoy immunity in the absence of a federal finding of . . . fraud on the FDA" to "the situation urged by the Plaintiff where drug manufacturers would enjoy no immunity at all." *Id.* The court of appeals relied on the Michigan severance provisions to support this holding. *Id.* at 966-67. Because

the State of Michigan is in the Sixth Circuit, that court's interpretation of the Michigan statute is entitled to deference. Its decision to find partial preemption is a federal question that was correctly decided under *Buckman*.[9]

A Michigan appellate court adopted *Garcia's* "holding that the fraud on the FDA exception is preempted by federal law unless the FDA itself determines that it was defrauded," and also agreed with its Michigan law holding regarding severance of the preempted portion of the statute. *Duronio v. Merck & Co., Inc.*, No. 267003, 2006 WL 1628516, at *5 (Mich. Ct. App. June 13, 2006). *Accord, Zammit v. Shire US, Inc.*, 415 F. Supp. 2d 760 (E.D. Mich. 2006).

The recurring nature of the issue presented by the conflict between *Garcia* and the Second Circuit is illustrated by the decisions cited in note 7, *supra*, addressing preemption of analogous state statutes, which followed the Sixth Circuit, and another that adopted the narrow view of the Second Circuit in finding no preemption of an analogous provision in a Texas statute.

The Second Circuit's Decision Below—The Second Circuit essentially rejected this Court's rationale in *Buckman* at every step of its opinion. App. 1a-28a.

First, the Second Circuit applied a presumption against federal preemption because the "Michigan legislature's desire to rein in state-based tort liability falls squarely within the prerogative to 'regulat[e] matters of public health and safety . . . .' " App. 19a. This argument flies in the face of *Buckman* and this Court's preemption case law discussed in that opinion, which hold that there is no presumption against preemption when

[9] The Sixth Circuit's interpretation of Michigan law is controlling in other circuits. *Factors Etc., Inc. v. Pro Arts, Inc.*, 652 F.2d 278 (2d Cir.1981), cited by the court of appeals below at App. 11a.

the state legislates regarding "the relationship between a federal agency and the entity it regulates," which relationship is "inherently federal in character." *Buckman*, 531 U.S. at 347. This case is sharply distinguishable from the state law claims in *Medtronic*, on which the Second Circuit relied (App. at 21a-22a), all of which predated the federal regulatory enactments, and did not interfere in any way with regulatory oversight over fraud investigations and enforcement.

Moreover, the Second Circuit's analysis is flawed because it treats Michigan's purpose as decisive, whereas *Buckman* focuses on the conflict with federal regulatory authority in an inherently federal area, without regard to the state's purpose. In addition, the Second Circuit's assertion fails to acknowledge that *Garcia* allows the state to "rein in" tort liability *and* to have an exception for fraud-on-the-FDA where the FDA has found fraud on the agency. The Sixth Circuit limited its preemption holding to cases where the fact-finder in a state-law action is required to find fraud-on-the-FDA as a condition to liability. That results in a state intrusion into "policing" fraud against a federal agency because, according to *Buckman*, the FDA has exclusive authority to decide whether there was a fraud on the agency and what consequences should follow.

The court below latched onto *Buckman*'s reference to the state law claim there being "solely" based on defrauding the FDA. But under the Michigan statute, product liability claims can succeed *only* if there is fraud-on-the-FDA—without which FDA would not have approved or would have withdrawn approval of the drug—*and* the product is proved defective. It is not sensible to suggest that by imposing the very same requirement of fraud-on-the-FDA and adding another requirement, a state law interferes with the FDA's regulatory policies any less than does

a statute requiring only fraud-on-the-FDA. The consequences to the federal regulatory process of a dual state/federal regime for finding fraud, and whether the fraud impacted regulatory approval, make this a difference without a distinction. *Buckman's* preemption rationale applies to all state law litigation of fraud-on-the-FDA, whether by statute or by a common law fraud claim.

Next, the court below purported to distinguish *Buckman* on the ground that plaintiffs here did not assert "fraud-on-the-FDA" claims. App. 19a-23a. However, preemption in *Buckman* did not turn on the *name* given to the state law requirement, but on the requirement itself and its intrusion into the FDA's exclusive authority over whether an applicant committed fraud against the agency. Furthermore, the court below wrongly concluded that the Sixth Circuit had "gutted" plaintiffs' traditional state law claims. App. 20a. The Michigan legislature—not the Sixth Circuit—altered the state's product liability regime.

The narrow procedural focus of the Second Circuit below is evident in its statement that under the Michigan statute, "FDA approval becomes germane *only* if a defendant company chooses to assert an affirmative defense made available by the Michigan legislature . . . ." App. 23a (emphasis in original). This statement is off the mark for two reasons. First, *Garcia* held—under Michigan law—that to invoke the exception, "*plaintiff* asks a court to find bribery or fraud on the FDA," 385 F. 3d 966 (emphasis added). The Michigan Supreme Court has characterized the fraud-on-the-FDA statutory exception as a "claim" that plaintiff must "make." *Taylor v. Smithkline Beecham Corp.*, 658 N.W.2d 127, 131 (Mich. 2003). Secondly, all of the concerns in *Buckman* remain whether FDA approval is raised as part of a plaintiff's prima facie case—as is

implicit in Plaintiffs' allegations here that fraud-on-the-FDA led to its approval of Rezulin—or, as a defense.

Moreover, where, as here, Plaintiffs alleged fraud-on-the-FDA in order to satisfy the statute's requirement, it follows that such fraud is an element of their state law claims. Furthermore, because the statutory requirement to prove fraud-on-the-FDA arises whenever there is an FDA-approved drug, which is a matter of public record and indisputable, it is immaterial whether that requirement is characterized as part of plaintiff's claim or as a rebuttal to a defense.

If a state created its own administrative agency to monitor and sanction fraud-on-the-FDA, the conflict between the state system and the federal interest would be unquestioned. *Buckman* held that this conflict is not lessened because the state seeks to regulate fraud through private litigation. Indeed, judicial intervention in the FDA regulatory process is likely to be even more intrusive as different state courts and juries potentially make different findings on what is required in the federal regulatory process, on when applicants have not satisfied those requirements, and on whether any omissions would have caused the federal agency to deny approval.

Finally, the Second Circuit brushed aside *Buckman*'s emphasis on "practical concerns" that would adversely impact the regulatory process, because—according to the Second Circuit—the same concerns purportedly would arise if a state court or jury were allowed to consider evidence of fraud-on-the-FDA. App. 24a. That possibility was as true in *Buckman* as it is here. To avoid disastrous effects on the regulatory process, *Buckman* has been properly applied so that evidence in the trial of common law or statutory claims "will be excluded outright when it is offered only to show that the FDA was misled, or that information was intentionally concealed

from the FDA." *Bouchard v. American Home Products Corp.*, 213 F. Supp. 2d 802, 812 (N.D. Ohio 2002). Moreover, the exception in the Michigan statute goes beyond allowing evidence of fraud-on-the-FDA, and in addition permits state law findings of fraud and materiality, which can be inconsistent with the FDA's position.

II. THE CIRCUIT SPLIT WILL LEAD TO CONSEQUENCES TO THE FEDERAL REGULATORY SCHEME, WHICH *BUCKMAN* SOUGHT TO AVOID.

By opening the door to inevitable inconsistencies between state and FDA determinations of fraud on the agency, the Second Circuit's decision will have a negative impact on the FDA's drug review process and its administration of the FDCA, which in turn will interfere with the FDA's mission to protect public health. *See Buckman*, 531 U.S. at 350. The FDA has "complete discretion" in addressing possible statutory or regulatory violations. *See Heckler v. Chaney*, 470 U.S. 821, 835 (1985). Under the Second Circuit's decision, state law findings of fraud-on-the-FDA might conflict not only with those of other states, but also with FDA's own determinations. For example, if the FDA denied a Citizen Petition asking the agency to find that an applicant committed fraud-on-the-FDA, a state court or jury could—under the Michigan statute—second guess FDA's finding. If FDA found no fraud, any state law decision that found fraud, pursuant to statute or at common law, would undermine public confidence in the FDA, thereby creating havoc in the regulatory process. *See Garner v. Teamsters*, 346 U.S. 485, 490-91 (1953) ("multiplicity of tribunals and a diversity of procedures are quite as apt to produce incompatible or conflicting adjudications as are different rules of substantive law").

Moreover, allowing state law determinations of fraud-on-the-FDA would distort the behavior of regulated entities, which up to now could base their interactions with the agency on federal requirements alone rather than those of numerous state courts. Under the FDCA and FDA regulations, the applicant must closely cooperate with FDA to determine how clinical trials are to be run and what data must be submitted. Superimposing a state law regime based on litigation in civil court actions will grind that interactive process to a halt if—at each of the many steps in the process—companies must consider not merely what FDA asks but what the states might have wanted the FDA to have. Moreover, state law determinations of fraud-on-the-FDA could distort the FDA's internal decision-making by tempting it to anticipate and respond to state court decisions. The FDA's control over clinical trials and related approval requirements is sufficiently complex today, that no additional expense, delay or confusion is warranted from state sources. *See Buckman*, 531 U.S. at 351. Indeed, the cost of research and development of a new drug, including the FDA approval process, has been estimated at $802 million.[10]

Furthermore, as the district court recognized in its opinion below, the Michigan statute threatens to embroil FDA in state court litigation. App. 35a-36a. Litigants naturally will seek out the best evidence of whether an agency has been defrauded and the impact of that fraud on approval. Plaintiffs and defendants will seek discovery on whether there was fraud and whether absent the fraud, the FDA would have withheld approval of the drug, or would have withdrawn its approval. This will necessitate combing through thousands of pages of NDA

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[10] Joseph A. DiMasi, Ronald W. Hansen, Henry G. Grabowski, *The Price of Innovation: New Estimates of Drug Development Costs*, 22 JOURNAL OF HEALTH ECONOMICS 151, 166 (2003).

material, followed by burdensome questioning of FDA personnel. Intrusive discovery into federal agency officials' states of mind, and the courses of action that agency officials might have taken under hypothetical scenarios long after the fact, would divert FDA resources from the central purpose assigned by Congress.

Nor would FDA personnel necessarily be shielded from testifying. FDA can decline to permit its employees to testify about their official duties, pursuant to 21 C.F.R. § 20.1. But courts do not always honor FDA's decisions in this regard. *See, e.g., In re Vioxx Prods. Liab. Litig.* 235 F.R.D. 334 (E.D. La. 2006) (denying FDA motion to quash deposition subpoena for FDA official). Moreover, if agency officials do not testify, juries would then be free to speculate on the key issues of fraud and what the agency might have done absent the fraud, which might conflict with the FDA's own judgment.

Notably, the Second Circuit ruling is at odds not just with a sister circuit, but with the circuit having the most direct responsibility for hearing claims arising under Michigan statutory law. The conflict in circuits should be resolved so that Michigan residents are not encouraged to sue in a distant forum within the Second Circuit, which they could do—given nationwide jurisdiction over pharmaceutical manufacturers—to nullify the sound decision of the Sixth Circuit. The conflict also will inject forum shopping considerations into the MDL process, which today handles much of the pharmaceutical product liability litigation.

This Court should clarify the law for state legislatures, state courts and lower federal courts by granting this petition and ruling that federal law preempts any state law to the extent it requires a fact-finder, in the absence of a fraud finding by the FDA, to determine under state

law whether a pharmaceutical manufacturer has committed a fraud-on-the-FDA that resulted in approval of a prescription drug. The disruption of the FDA administrative and regulatory process that *Buckman* sought to avoid will reappear if this conflict is not resolved by a sensible and functional application of this Court's preemption pronouncements.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted,

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Dated: May 10, 2007

APPENDIX

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UNITED STATES COURT OF APPEALS

FOR THE SECOND CIRCUIT

August Term, 2005

(Argued: November 8, 2005

Decided: October 5, 2006

Amended: January 18, 2007)

Docket Nos. 05-1705-cv(L), 05-1743-cv(CON), 05-1745-cv(CON)

CAESAR DESIANO ET AL.,

Plaintiffs-Appellants,

—v.—

WARNER–LAMBERT & CO., ET AL,

Defendants-Appellees.

Before:

FEINBERG, CALABRESI, and B.D. PARKER,

Circuit Judges.

Appeal from grant of judgment on the pleadings in favor of Defendants-Appellees. The United States District Court for the Southern District of New York (Kaplan, J.) held that Michigan law shields pharmaceutical companies from products liability claims unless

there is, *inter alia*, evidence that the drug company misrepresented or withheld material information in obtaining FDA approval for its drug. The court concluded that Michigan plaintiffs' claims could not be distinguished from the "fraud-on-the-FDA" claim found to be preempted by federal law in *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001). We disagree. A presumption against federal preemption of state law applies in the context of traditional common law claims preserved by states to protect the health and safety of their citizens. Moreover, a fraud-based exception to Michigan's immunity statute does not raise the same concerns that animated the Supreme Court's decision in *Buckman*. Vacated and remanded.

DAVID B. RODES, Goldberg, Persky & White, P.C., Pittsburg, PA (Vincent J. Carter, Girardi Keese, Los Angeles, CA; David R. Parker, Charfoos & Christensen, PC, Detroit, MI; Jerome D. Goldberg, Varjabedian Attorneys, Southfield, MI, *on the brief*), *for Plaintiffs-Appellants*.

DAVID KLINGSBERG, Kaye Scholer LLP (Wendy S. Dowse, *on the brief*), New York, NY, *for Defendants-Respondents*.

CALABRESI, *Circuit Judge*:

It has long fallen within the province of states to safeguard the health and safety of their citizens. *See Medtronic v. Lohr*, 518 U.S. 470, 475 (1996). Consonant with the "historic primacy of state regulation" of

these matters, *see Medtronic*, 518 U.S. at 485, the power of states to govern in this field is considerable and undisputed. *See Metropolitan Life Ins. Co. v. Massachusetts*, 471 U.S. 724, 756 (1985) ("The States traditionally have had great latitude under their police powers to legislate as 'to the protection of the lives, limbs, health, comfort, and quiet of all persons.'" (quoting *Slaughter-House Cases*, 16 Wall. 36, 62, 21 L.Ed. 394 (1873); *Thorpe v. Rutland & Burlington R. Co.*, 27 Vt. 140, 149 (1855)). Historically, common law liability has formed the bedrock of state regulation, and common law tort claims have been described as "a critical component of the States' traditional ability to protect the health and safety of their citizens." *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 544 (1992) (Blackmun, J., concurring in part and dissenting in part). In recent years, some states, in exercising their traditional authority with respect to the pharmaceutical industry, have narrowed common law liability in order to insulate drug companies from burdensome litigation. *See generally* David G. Owen, *Special Defenses in Modern Products Liability Law*, 70 MO. L. REV. 1, 22-23 (2005). The case before us concerns a supposed conflict between federal law and the products liability regime of one such state.

In 1995, the State of Michigan enacted legislation immunizing drugmakers from products liability claims so long as the Food and Drug Administration ("FDA") approved the pharmaceutical product at issue. *See* Mich. Comp. Laws § 600.2946(5) (hereinafter "M.C.L. § 2946(5)"). Michigan's immunity scheme contains an exception that preserves liability if the pharmaceutical company withheld or misrepresented information that would have altered the FDA's decision to approve the drug. In 2001, in a case dealing with different legal

rules and a different jurisdiction, the Supreme Court held that state "fraud-on-the-FDA" claims were impliedly preempted by federal law. *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 348 (2001). The question presented by this appeal is whether, under the rationale of *Buckman*, federal law also preempts traditional common law claims that survive a state's legislative narrowing of common law liability through a fraud exception to that statutory limitation. For the reasons below, we conclude that federal law does not preempt these state claims. We therefore vacate the District Court's grant of judgment on the pleadings and remand the case for further proceedings consistent with this opinion.

BACKGROUND

A. Michigan's Immunity Statute

Prior to its amendment in 1995, Michigan's products liability statute provided that "evidence showing compliance with governmental or industry standards was admissible in a products liability action in determining if the standard of care had been met." *Taylor v. Smithkline Beecham Corp.*, 658 N.W.2d 127, 130 (Mich. 2003). In describing the pre-amendment law, the Supreme Court of Michigan emphasized the limits on the probative value of this sort of evidence of compliance:

> We note that our Legislature has recently enacted a statute which provides that industrial and governmental standards are admissible in products liability actions [citing earlier version of M.C.L. § 600.2946]. The statute does not provide that such standards are con-

> clusive. [We affirm the position] that compliance with governmental and industrial standards is admissible as evidence but is not conclusive as to whether the defendant was negligent or the product was defective.

Owens v. Allis-Chalmers Corp., 326 N.W.2d 372, 375-76 (Mich. 1982).

In 1995, Michigan's legislature amended the law in order to confer immunity upon drugmakers in product liability suits where the FDA had approved the drug in question. *See Taylor*, 658 N.W.2d at 130 ("The 1995 amendment of the statute . . . provided that compliance with federal governmental standards (established by the FDA) is conclusive on the issue of due care for drugs."). The relevant provision states:

> In a product liability action against a manufacturer or seller, a product that is a drug is not defective or unreasonably dangerous, and the manufacturer or seller is not liable, if the drug was approved for safety and efficacy by the United States food and drug administration, and the drug and its labeling were in compliance with the United States food and drug administration's approval at the time the drug left the control of the manufacturer or seller.

M.C.L. § 2946(5). In addition to several qualifications not relevant to the case before us,[1] the immunity provision contains an important exception:

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[1] Michigan's law also states that the immunity "subsection does not apply to a drug that is sold in the United States after the effective date of an order of the United States food and drug administration to remove the drug from the market or to withdraw its approval." M.C.L. § 2946(5). And the immunity "does not apply if the defendant at any

> This subsection does not apply if the defendant at any time before the event that allegedly caused the injury does any of the following:
>
> (a) Intentionally withholds from or misrepresents to the United States food and drug administration information concerning the drug that is required to be submitted under the federal food, drug, and cosmetic act and the drug would not have been approved, or the United States food and drug administration would have withdrawn approval for the drug if the information were accurately submitted.

M.C.L. § 2946(5)(a) (internal citations omitted). Hence, under these provisions, so long as a drug company did not withhold or misrepresent information that would have affected the FDA's approval of a putatively harmful drug, the company can successfully defend itself against products liability litigation by establishing that its product received the FDA's approval and complied with the FDA's labeling and substantive requirements.

B. Procedural History

Appellants in this case are all Michigan residents alleging injuries caused by Rezulin, a drug marketed and sold by Appellees for the treatment of Type-2 diabetes. The FDA originally approved Rezulin in 1997. After adverse liver-related effects were docu-

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time before the event that allegedly caused the injury . . . [m]akes an illegal payment to an official or employee of the United States food and drug administration for the purpose of securing or maintaining approval of the drug." M.C.L. § 2946(5)(b).

mented in patients taking Rezulin, Appellees agreed to a series of label changes, which were authorized by the FDA on four occasions between November 1997 and June 1999. In March 2000, apparently at the FDA's request, *see Desiano v. Warner-Lambert Co.*, 326 F.3d 339, 344 (2d Cir. 2003), Appellees withdrew Rezulin from the United States market.

The instant litigation began in state courts in Michigan and California. Appellants asserted various common law claims including, *inter alia*, breach of implied and express warranties, negligence, negligent misrepresentation, negligence *per se*, fraud, defective design, defective manufacturing, and loss of consortium. The drug companies removed the actions to federal court, and all of the claims were subsequently consolidated and transferred by the Judicial Panel on Multidistrict Litigation to Judge Lewis A. Kaplan in the Southern District of New York.

In the District Court, Appellees moved for judgment on the pleadings on the ground that liability was foreclosed under Michigan state law. To support their motion, Appellees emphasized *Buckman* and the Sixth Circuit's decision in *Garcia v. Wyeth-Ayerst Labs.*, 385 F.3d 961 (6th Cir. 2004), which held (on the basis of *Buckman*) that the "fraud" exception in Michigan's statute was impliedly preempted by two federal laws —the Food, Drug and Cosmetic Act ("FDCA"), 21 U.S.C. § 301, *et seq.*, and the Medical Device Act ("MDA"), 21 U.S.C. §§ 360e(b)(1)(A)-(B)—and therefore had to be severed from the rest of the Michigan law.

The District Court agreed with Appellees, concluding that the immunity exception should be severed because under the reasoning of *Buckman*, it was pre-

empted by federal law.[2] The court gave two reasons for its decision. First, the District Court believed that, although it was not "absolutely bound" by *Garcia*, the Sixth Circuit's reasoning was owed "quite substantial deference" under *Factors Etc., Inc. v. Pro Arts, Inc.*, 652 F.2d 278 (2d Cir. 1981), a decision by a panel of this circuit which stated that conclusive deference should be given to a federal court of appeals' interpretation of the law of a state within its circuit. Second, "apart from *Factors*," the District Court reasoned that "[i]f plaintiffs covered by the Michigan statute were able to litigate claims of fraud on the FDA in individual personal injury suits, whether in state courts or in federal courts, the potential would exist for the FDA's personnel to be drawn into those controversies on a case-by-case basis over and over again." Concluding that this would generate "a wholly impractical situation," the court held "that the exception in the Michigan statute is preempted, except where the plaintiff relies on a finding by the FDA, or in an action brought by the FDA, of material fraud in the new drug approval process absent which approval would not have been granted." Hence, the court granted the drugmakers' motion for judgment on the pleadings and dismissed all of Appellants' complaints.

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[2] Before addressing the preemption issue, Judge Kaplan considered the choice-of-law question for those claims originally filed in California state court and concluded that there was "no serious argument for the application of California substantive law." In fact, the attorney representing those Michigan residents who filed suit in California conceded that he was the only tie his clients had to California. Moreover, Judge Kaplan observed that California's choice-of-law provisions required that the case be governed by the law of Michigan, where the plaintiffs reside and where the alleged injuries took place. None of the parties have challenged this finding on appeal.

Appellants filed a timely appeal.

DISCUSSION

We review *de novo* a district court's dismissal of a suit pursuant to a motion for judgment on the pleadings. *See King v. Am. Airlines, Inc.*, 284 F.3d 352, 356 (2d Cir. 2002); *Burnette v. Carothers*, 192 F.3d 52, 56 (2d Cir. 1999). "In deciding a Rule 12(c) motion, we apply the same standard as that applicable to a motion under Rule 12(b)(6), accepting the allegations contained in the complaint as true and drawing all reasonable inferences in favor of the nonmoving party." *Burnette*, 192 F.3d at 56.

This appeal raises two separate and significant questions. First, under the rule in *Factors*, must we follow our sister circuit's holding in *Garcia* because the Sixth Circuit's decision involved the laws of Michigan, a state within its circuit? Second, even if we are not required to defer conclusively to *Garcia*, should we nonetheless conclude, applying the logic of *Buckman*, that Appellants' common law claims—preserved by Michigan's exception—conflict with, and are therefore preempted by, federal law?

I.

The District Court interpreted *Factors* to mean that, although it was not "absolutely bound" by the Sixth Circuit's ruling, *Garcia* was owed "substantial deference." Appellees advocate an interpretation of *Factors* that insists upon more than deference. They contend that, under *Factors*, we are not free to reach a conclusion contrary to *Garcia* unless a different result is compelled by prior or subsequent pronouncements of

the Supreme Court of Michigan. For their part, Appellants do not identify any contrary Michigan law to refute the *Garcia* court's decision that federal law preempts Michigan's immunity exception.[3] As a result, Appellees maintain that *Garcia* binds us to dismiss Appellants' suit. Appellees may be correct in their reading of *Factors*, when it applies. But like the District Court they misgauge the relevance of *Factors* to the case before us.

Factors involved a contract dispute governed exclusively by Tennessee state law. In that context, we held that a federal court exercising diversity jurisdiction should give "conclusive deference" to "a ruling by a court of appeals deciding the law of a state within its circuit." *Factors*, 652 F.2d at 279. We elaborated that conclusive deference was owed except in very narrow circumstances:

> We need not and do not conclude that the state law holding of the pertinent court of appeals is automatically binding upon the federal courts of all the other circuits. The ultimate source for state law adjudication in diversity cases is the law as established by the constitution, statutes, or authoritative court decisions of the state. A federal court in another circuit would be obliged to disregard a state law holding by the pertinent court of appeals if persuaded that the holding had been superseded by a later pronouncement from state legislative or judicial sources, or that prior

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[3] Appellants' arguments against preemption rely mainly on federal precedent. The only Michigan case they focus on, *Maki v. East Tawas*, 188 N.W.2d 593 (Mich. 1971), bears solely on severability, not preemption.

> state court decisions had been inadvertently overlooked by the pertinent court of appeals.

Factors, 652 F.2d at 283 (internal citation omitted). Because neither of these circumstances applied to the sister circuit's decision—*i.e.*, the court of appeals' decision had not been weakened by subsequent developments in state law, nor was the decision contrary to prior state precedent—the *Factors* court mandated deference:

> Where, as here, the pertinent court of appeals has essayed its own prediction of the course of state law on a question of first impression within that state, the federal courts of other circuits should defer to that holding, perhaps always, and at least in all situations except the rare instance when it can be said with conviction that the pertinent court of appeals has disregarded clear signals emanating from the state's highest court pointing toward a different rule.

Factors, 652 F.2d at 283.

But *Factors* instructed us to defer conclusively to another circuit's judgment only when that court of appeals' decision addressed questions of *state* law from a state within that circuit. It asserted no obligation to defer to a foreign circuit's views on *federal* law. As to issues of federal law, we are permitted—indeed, required—to reach our own conclusions. *See Pan Am. World Airways, Inc. v. C. A. B.*, 517 F.2d 734, 741 (2d Cir. 1975) ("[W]e are not bound by the decision or the rationale of [another circuit] court."); *see also Colby v. J.C. Penney Co., Inc.*, 811 F.2d 1119, 1123 (7th Cir. 1987) ("We have an intermediate obligation to our sister federal courts of appeals. Bearing in mind the

interest in maintaining a reasonable uniformity of federal law and in sparing the Supreme Court the burden of taking cases merely to resolve conflicts between circuits, we give most respectful consideration to the decisions of the other courts of appeals and follow them whenever we can. Our district judges should, of course, do likewise with regard to such decisions . . . . But neither this court nor the district courts of this circuit give the decisions of other courts of appeals automatic deference; we recognize that, within reason, the parties to cases before us are entitled to our independent judgment." (internal citation omitted)).

This obligation does not change in the context of transferred cases. In *Menowitz v. Brown*, 991 F.2d 36 (2d Cir. 1993) (per curiam), we considered securities fraud claims that had been consolidated and transferred to the Southern District of New York only to be dismissed as untimely under our circuit's limitations guidelines. One set of claims, however, had originally been filed in the Southern District of Florida and would have been timely under the statute of limitations applicable under the Eleventh Circuit's rule (which would have borrowed Florida's "blue sky" limitations period). Thus, the question presented was "whether Second Circuit doctrine directs application of the Eleventh Circuit limitations rule to such a transferred action." *Menowitz*, 991 F.2d at 40. We stated that "[r]esolution of this question turns on whether the choice of the applicable limitations period is properly understood as a matter of state or of federal law." *Id.* Were it an issue of state law, we indicated that "a transferee court applies the substantive state law, including choice-of-law rules, of the jurisdiction in which the action was filed." *Id.* But since we concluded

that the proper statute of limitations applicable to a federal claim was a matter of federal law, we disregarded the Eleventh Circuit's approach to the federal issue and opted instead to follow our own. In so doing, we emphasized that, even in the transfer context, a court of appeals must develop its own circuit law on federal questions; it cannot mechanically adopt the reasoning and conclusions of its sister circuits:

> We have previously held that a transferee federal court should apply its interpretations of federal law, not the constructions of federal law of the transferor circuit. . . . [F]ederal courts comprise a single system applying a single body of law, and no litigant has a right to have the interpretation of one federal court rather than that of another determine his case.
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> . . .
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> [U]ntil the Supreme Court speaks, the federal circuit courts are under duties to arrive at their own determinations of the merits of federal questions presented to them; . . . [I]f a federal court simply accepts the interpretation of another circuit without [independently] addressing the merits, it is not doing its job.

Id. (internal citations and quotation marks omitted).

The problem, therefore, with the District Court's decision and with the position taken by Appellees is that both fail to appreciate that this appeal—unlike the Tennessee contract dispute in *Factors*—is not governed primarily, and certainly not exclusively, by state law. Rather, the question of whether federal law impliedly preempts part of Michigan's statutory scheme depends on significant issues of federal law including, *inter alia*, the meaning of Supreme Court

precedents, *e.g.*, *Buckman*, and the scope of federal statutes, *e.g.*, FDCA. As a result, in resolving this appeal, we operate under twin mandates with respect to the Sixth Circuit's opinion in *Garcia*. On the one hand, under *Factors*, we are bound to follow *Garcia*'s conclusions as to questions of Michigan state law. On the other hand, under *Menowitz*, we are obligated to answer independently questions of federal law, applying only the usual intercircuit regard for the Sixth Circuit's analysis of these federal issues.

Accordingly, the central question presented by this appeal—*i.e.*, whether federal law preempts Michigan's immunity exception—is controlled by the decision in *Garcia* only to the extent that the Sixth Circuit's conclusion rested solely on findings as to state law. *Garcia* did begin with an explanation of state law:

> [M.C.L. § 2946(5)] presents a somewhat different legal regime from the one invalidated in *Buckman*. The Michigan legislature has provided a general immunity for drug manufacturers with a specific exception for circumstances involving, *inter alia*, fraud on the FDA rather than a specific cause of action for fraud on the FDA.

Garcia, 385 F.3d at 965-66 (internal footnote omitted). Under *Factors*, therefore, we must accept the Sixth Circuit's conclusion that M.C.L. § 2946(5) *does not* create a new cause of action for misleading the FDA. And that holding guides our review of the federal issues before us.[4]

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[4] It should be noted that *Factors*, a case involving Tennessee state law, was decided in 1981. At that time, the Tennessee Supreme Court did not accept certified questions. *See Holt by Holt v. Hypro, a Div. of Lear Siegler, Inc.*, 746 F.2d 353, 354 (6th Cir. 1984) ("We[, the Sixth

After issuing this interpretation of M.C.L. § 2946(5), the Sixth Circuit turned to issues of federal law. And, on the basis of *its* understanding of the Supreme Court's decision in *Buckman*, the Sixth Circuit concluded that the difference it had just identified —between those preexisting common law claims that survived M.C.L. § 2946(5) and those arising under a specific cause of action for fraud-on-the-FDA, like those invalidated in *Buckman*—was "immaterial." *See Garcia*, 385 F.3d at 966 ("As the [Michigan] district

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Circuit,] are somewhat puzzled by the [Tennessee] statute as it applies to minors injured by products over ten years old, and we sought to certify the question to the Tennessee Supreme Court. That Court has now advised us that they do not have the judicial power to accept certified questions. We are left to divine the meaning of the Tennessee Legislature on our own."). In fact, it was not until 1989 that Tennessee adopted a certification rule. *See* Tennessee Supreme Court Rule 23 ("The Supreme Court may, at its discretion, answer questions of law certified to it by the Supreme Court of the United States, a Court of Appeals of the United States, a District Court of the United States in Tennessee, or a United States Bankruptcy Court in Tennessee.") (made effective February 17, 1989). It may well be, therefore, that *Factors* would not foreclose us from certifying a question of state law to the relevant state court, even where the pertinent federal court of appeals has provided its interpretation.

We need not, and hence do not, however, decide in this case the significance of *Factors* when certification is available and appropriate. Certification to Michigan is available. *See* Michigan Court Rule 7.305(B)(1) ("When a federal court, state appellate court, or tribal court considers a question that Michigan law may resolve and that is not controlled by Michigan Supreme Court precedent, the court may on its own initiative or that of an interested party certify the question to the Michigan Supreme Court."). But *Garcia*'s holding that the state law at issue in this case does not *create* a new cause of action is so clearly correct, both on its face, and in view of the relationship of the current statute to the previous Michigan law (which allowed defendants to introduce evidence of compliance with government standards, *Taylor*, 658 N.W.2d at 130), that certification would not be appropriate.

court properly found, '*Buckman* teaches that state tort remedies requiring proof of fraud committed against the FDA are foreclosed since federal law preempts such claims.' ").

Nothing in *Factors* requires that we adopt the Sixth Circuit's reading of *Buckman*. On the contrary, because *Garcia*'s conclusions as to preemption depended on its analysis of federal (and not state) law, we must decide for ourselves whether Michigan's surviving common law cause of action is implicitly preempted by federal law under the rationale of *Buckman*. It is to this question that we, therefore, now turn.

II.

In *Buckman*, the Supreme Court considered whether federal law—specifically, the FDCA and the MDA —pre-empted state "fraud-on-the-FDA" claims. The plaintiffs in *Buckman* contended that a medical device manufacturer had obtained FDA approval for its product only after making fraudulent misrepresentations to the federal agency. Claiming that the FDA would not have approved the device but for these misrepresentations, the plaintiffs sought damages under California state law. The Court began by stating what is undoubtedly true that "[p]olicing fraud against federal agencies is hardly a field which the States have traditionally occupied." *Buckman*, 531 U.S. at 347 (internal citation and quotation marks omitted). As a result, the presumption against federal preemption of a state law cause of action did not apply to fraud-on-the-FDA claims. *Id.*

In the absence of any presumption against preemption, the Court found that fraud-on-the-FDA claims conflicted with, and were therefore impliedly pre-

empted by, federal law. "The conflict stems from the fact that the federal statutory scheme amply empowers the FDA to punish and deter fraud against the Administration, and that this authority is used by the Administration to achieve a somewhat delicate balance of statutory objectives." *Id.* at 348. In other words, *policing fraud on the FDA* through a tort action could interfere with how the FDA might wish to police that kind of fraud itself.

The *Buckman* Court went on to express its concern that the potential conflict between federal law and the competing regulatory regimes of 50 states would unduly burden drug companies seeking to obtain FDA approval for their products. The Supreme Court worried that these companies, fearful of state liability, would file "a deluge of information" that the FDA does not require, thereby burdening the federal agency as well. *Id.* at 351. But the Court ended by emphasizing that the plaintiffs' claims before it were not rooted in traditional state law, and were instead derivative of federal law:

> In sum, were plaintiffs to maintain their fraud-on-the-agency claims here, they would not be relying on traditional state tort law which had predated the federal enactments in questions. On the contrary, the existence of . . . federal enactments is a critical element in their case.

Id. At 353. For these reasons, the Court invalidated the plaintiffs' fraud-on-the-FDA claims as impliedly preempted by federal law.

Echoing the conclusion of the Sixth Circuit, Appellees argue that, notwithstanding *Garcia*'s statement that M.C.L. § 2946(5) did not create "a specific cause of action for fraud on the FDA," *Garcia*, 385 F.3d at

966, there is no meaningful difference between the fraud-on-the-FDA claims struck down in *Buckman* and Appellants' claims under Michigan tort law. We disagree. There are three differences between the nature of the claim which M.C.L. § 2946(5) exempts from abolition and the claim in *Buckman*. Given the bases of *Buckman*'s holding, each of these is crucial.

A. *Presumption Against Preemption*

First, the presumption against federal preemption of state law obtains in the case before us. In *Medtronic*, the Supreme Court explained that "because the States are independent sovereigns in our federal system, we have long presumed that Congress does not cavalierly pre-empt state-law causes of action." *Medtronic*, 518 U.S. at 485. In *Buckman*, the Court held that this presumption did not apply *because "[p]olicing fraud against federal agencies is hardly a field which the States have traditionally occupied." Buckman*, 531 U.S. at 347 (internal citation and quotation marks omitted) (emphasis added).

In the case before us, instead, the cause of action (which survives the changes made by M.C.L. § 2946(5)) cannot reasonably be characterized as a state's attempt to police fraud against the FDA. And, significantly, *Garcia* did not so characterize it. Rather, as *Garcia* recognized, M.C.L. § 2946(5) did not invent new causes of action premised on fraud against the FDA. The object of the legislative scheme was rather to regulate and restrict when victims could continue to recover under preexisting state products liability law.[5]

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[5] We also have found no evidence that the goal of preventing or punishing fraud against the FDA in any way motivated Michigan legislators to enact the statutory framework in question. M.C.L.

The Michigan legislature's desire to rein in state-based tort liability falls squarely within its prerogative to "regulat[e] matters of health and safety," which is a sphere in which the presumption against preemption applies, indeed, stands at its strongest. *See Buckman*, 531 U.S. at 348 (citing *Medtronic*, 518 U.S. at 485 as governing "situations implicating 'federalism concerns and the historic primacy of state regulation of matters of health and safety,' " and contrasting these to the case before it). As a result, while there may be reasons to override that presumption, the existence of the presumption in the instant case requires an altogether different analysis from that made in *Buckman*.[6]

B. Traditional Common Law Liability

Second, Appellants here are not pressing "fraud-on-the-FDA" claims, as the plaintiffs in *Buckman* were understood by the Supreme Court to be doing. They are, rather, asserting claims that sound in traditional state tort law. In *Buckman*, the Supreme Court mentioned two characteristics of preempted "fraud-on-the-

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§ 2946(5) grew out of Michigan Senate Bill 344; the "Bill Analysis," produced by the state Senate Fiscal Agency, suggests that the main impetus driving the legislation was a desire to limit the liability of drug makers under state tort law. *See generally* S. Fiscal Agency, SFA B. Analysis, Revised Enrolled Analysis, S.B. 344, H.B. 4508, at *1 (Jan. 11, 1996) ("According to many, over the past several decades there has been an explosion of product liability litigation, resulting in unfair and excessive judgments against manufacturers and sellers.... In Congress and state legislatures, a number of proposals have been advanced to reduce manufacturers' and sellers' exposure to liability.").

[6] This fact also substantially diminishes the persuasive effect of the federal law analysis made in *Garcia*, since the Sixth Circuit's holding in *Garcia* was based on the assumption that no presumption against preemption applied.

FDA" claims that distinguish them from claims sounding in preexisting common law.

The *Buckman* Court suggested that the source and "vintage" of the *duty* the drug maker is accused of breaching in "fraud-on-the-FDA" claims is different from the source and "vintage" of the duty that obtains in traditional tort claims. On this basis, the *Buckman* Court distinguished the plaintiff's unpreempted claims in *Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238 (1984), from those before it and wrote: "Silkwood's claim was not based on any sort of fraud-on-the-agency theory, but on traditional state tort law principles of the duty of care owed by the producer of plutonium fuel pins to an employee working in its plant." *Buckman*, 531 U.S. at 352.

Significantly, all of the claims advanced by Appellants in this case are premised on traditional duties between a product manufacturer and Michigan consumers. None of them derives from, or is based on, a newly-concocted duty between a manufacturer and a federal agency. As a result, were we to conclude that Appellants' claims were preempted, we would be holding that Congress, without any explicit expression of intent, should nonetheless be taken to have modified (and, in effect, gutted) traditional state law duties between pharmaceutical companies and their consumers. We see no reason, nor can we identify any precedent, to justify such a result.[7]

The second difference between common law actions and "fraud-on-the-FDA" claims, suggested in *Buckman*, is that in FDA-fraud cases, proof of fraud against the FDA is *alone sufficient* to impose liability. In

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[7] This may be seen as another way of saying that, unlike the situation in *Buckman*, the presumption against preemption is at its strongest in the instant case.

Buckman, there were no freestanding allegations of wrongdoing apart from the defendant's purported failure to comply with FDA disclosure requirements. And *Buckman* explicitly distinguished *Medtronic* on this ground. *Medtronic*, the *Buckman* Court said, involved a "common-law negligence action against the manufacturer of an allegedly defective" product:

> [T]he *Medtronic* claims arose from the manufacturer's alleged failure to use reasonable care in the production of the product, not *solely* from the violation of FDCA requirements. In the present case, however, the fraud claims exist *solely* by virtue of the FDCA disclosure requirements. Thus, although *Medtronic* can be read to allow certain state-law causes of actions that parallel federal safety requirements, it does not and cannot stand for the proposition that *any* violation of the FDCA will support a state-law claim.

Buckman, 531 U.S. at 352-53 (emphasis added) (internal citation omitted).

As in *Medtronic*, the plaintiffs' claims in the case before us "parallel federal safety requirements" but are not premised principally (let alone exclusively) on a drug maker's failure to comply with federal disclosure requirements. On the contrary, the plaintiffs' complaints allege a wide range of putative violations of common law duties long-recognized by Michigan's tort regime. These pre-existing common law claims survive under M.C.L. § 2946(5) because there is also evidence of fraud in FDA disclosures. But, unlike the claims in *Buckman*, they are anything but based *solely* on the wrong of defrauding the FDA. Given *Buckman*'s explanation of *Medtronic*, *Buckman* cannot be read as

precluding such preexisting common law liability based on other wrongs, even when such liability survives only because there was *also* evidence of fraud against the FDA.

Significantly, this reading of *Buckman* reflects the position the pharmaceutical industry articulated at oral argument in *Buckman*. Thus, the industry's presentation to the Supreme Court began by stressing the unusual and narrow claim before the *Buckman* Court:

> The plaintiffs in this case are people who underwent back surgery in which particular medical devices were used. They brought this suit under State law to recover for injuries allegedly caused by their—by these devices, but this is a very unusual form of State law product liability action. The plaintiffs don't claim that these devices were in any way defective. There's no claim here of manufacturing defect. There's no claim here of design defect. The plaintiffs also don't claim that the surgeons who used these devices did anything wrong. There's no claim here of medical malpractice.
>
> Instead, the plaintiffs' sole claim in this case is the following. They assert that the Federal Food & Drug Administration was deceived into giving regulatory clearance to these devices, that, absent this deception, these devices would never have been on the market, and that, if the devices had never have been on the market, they wouldn't have been used in their surgeries and they wouldn't have suffered any injuries.

Oral Argument Transcript, *Buckman*, 531 U.S. 341, 2000 WL 1801621, at *3-4 (2000) (No. 98-1768).[8]

C. Immunity as Affirmative Defense

Third, and once more unlike *Buckman*, the Michigan Supreme Court has indicated that proof of fraud against the FDA is not even an *element* of a products liability claim like the one here brought. The existence of properly-obtained FDA approval becomes germane *only* if a defendant company chooses to assert an affirmative defense made available by the Michigan legislature in M.C.L. § 2946(5). *See Taylor*, 658 N.W.2d at 131. Thus, in *Taylor*'s discussion of M.C.L. § 2946(5), Michigan's highest court offered this characterization of the statute: "[A] manufacturer or seller of a drug that has been approved by the FDA has an absolute *defense* to a products liability claim if the drug and its labeling were in compliance with the FDA's approval at the time the drug left the control of the manufacturer or seller." *Id.* (emphasis added). And, throughout its opinion, the *Taylor* court spoke of the *defendant's* references to the *FDA's* findings, suggesting again that it is the defendant that must invoke the FDA's decision to approve its drug if it wishes to

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[8] Similarly, a second lawyer for the industry indicated that traditional tort remedies were *not* implicated by *Buckman*. When asked about what remedies an injured plaintiff would have under his theory of the case, the attorney responded: "The *fraud* claim is preempted, but if there is negligent design, negligent manufacturing, failure to warn, common law malpractice, all of those claims are available . . . ." *Id.* at 21 (emphasis added). In the case before us, Appellants have asserted precisely "negligent design, negligent manufacturing, [etc.] . . ." and claim only that the Michigan exclusion from liability does not apply to their traditional tort law claims because there was *also* fraud on the FDA.

insulate itself from liability, *Taylor*, 658 N.W.2d at 134. We take this to mean that the Michigan law in question does no more than create a defense that drug makers may invoke, if they so decide, and that it is not up to the plaintiff to prove fraud as an element of his or her claim.

Finding preemption of traditional common law claims where fraud is not even a required element—but may be submitted to neutralize a drugmaker's use of an affirmative defense available under state law—would result in preemption of a scope that would go far beyond anything that has been applied in the past. Until and unless Congress states explicitly that it intends invalidation of state common law claims merely because issues of fraud may arise in the trial of such claims, we decline to read general statutes like the FDCA and the MDA as having that effect. *See Medtronic*, 518 U.S. at 485 ("[P]articularly in [circumstances] in which Congress has 'legislated . . . in a field which the States have traditionally occupied,' we 'start with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the *clear and manifest* purpose of Congress.'" (internal citations omitted) (emphasis added)).

* * *

The *Buckman* Court did, however, mention practical concerns with allowing "fraud-on-the-FDA" suits to go unpreempted. Specifically, it said that permitting such suits would result in a deluge of information that could swamp FDA administrators. The *Garcia* court, in applying *Buckman* to a suit like the one before us, made reference to these same concerns. But these worries, if deemed controlling, would prove too much.

They would result in preemption of a scope that no one is contemplating, let alone advocating.

In terms of deluging the FDA, there is little difference between (a) causes of action, like the instant one, where proof of fraud against the FDA is not the basis of the cause of action but is necessary to negate a limitation on state liability, and (b) causes of action where proof of fraud against the FDA is permitted but not conclusive (as it was under the precursor to the Michigan law at issue here, *see supra*, and as it presumably is in most states in the country). So long as a court or jury is *allowed to consider* evidence of fraud against the FDA in an ordinary common law tort suit, and so long as juries are likely to react to such evidence, there will be substantial inducements on the pharmaceutical industry to provide the federal agency with just the kind of information that troubled the *Buckman* and *Garcia* Courts. Requiring such evidence when a plaintiff seeks to counter a statutory defense from liability would not significantly alter that incentive. Only when proof of fraud is by itself *sufficient* to impose liability—and indeed is the sole basis of liability (as it was in *Buckman*)—does the incentive to flood the FDA appreciably escalate.

In other words, the incentive to supply additional data to the FDA under the Michigan law before us is no greater than the incentive that exists whenever evidence of what a company submitted, or failed to submit, to the FDA is admissible and probative of liability. It follows that under *Garcia*'s reading of *Buckman*, unless a state barred the submission of evidence of fraud against the FDA in run of the mill tort cases, the policy concerns that *Buckman* expressed in a very narrow context would seemingly justify invalidating any product liability suit brought against

a drugmaker. We do not believe *Buckman* meant to go anywhere near so far.[9]

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[9] Since we heard oral argument in this case, the FDA issued a final rule governing the content and format of drug product labeling. *See* 71 Fed. Reg. 3922 (Jan. 24, 2006). In the amended regulation, the FDA announced its view that FDA labeling requirements preempt state law claims that impose additional or different requirements: "[The] FDA believes that under existing preemption principles, FDA approval of labeling under the act, whether it be in the old or new format, preempts conflicting or contrary State law." *Id.* at 3934. In so doing, the FDA apparently confined its view that state claims undermine federal law to circumstances "when [state laws] purport to compel a firm to include in labeling or advertising a statement that [the] FDA has considered and found scientifically unsubstantiated." *Id.* at 3935.

Although any statement by a federal agency carries persuasive weight, the FDA's recent pronouncement does not ultimately affect our analysis in this case. The FDA's statement concerns only preemption of state laws that impose additional *labeling* requirements. Appellants' claims rest on far broader allegations, *e.g.*, defective design and manufacturing.

To the extent that the FDA's statement might bear peripherally on the claims asserted in this case, it is not clear what, if any, deference would be owed to the FDA's view. Assertions of implied preemption arguably originate in statutory ambiguity as to which an agency's interpretations may be accorded deference. *See generally Chevron U.S.A, Inc. v. Natural Res. Def. Council*, 467 U.S. 837 (1984). And—at least in a field of regulation in which no presumption against preemption applies—we recently indicated that we will give *Chevron* deference to an agency's regulation even though its interpretation has the resultant effect of preempting state law. *See Wachovia Bank, N.A. v. Burke*, 414 F.3d 305, 314-15 (2d Cir. 2005).

But, whatever deference would be owed to an agency's view in contexts where a presumption against federal preemption does apply, it is arguable that an agency cannot supply, on Congress's behalf, the clear legislative statement of intent required to overcome the presumption against preemption. *Cf. Alexander v. Sandoval*, 532 U.S. 275, 291 (2001) ("Agencies may play the sorcerer's apprentice but not the sorcerer himself."). Because we find that a presumption against preemption applies in the instant case, it may also be argued that even

III.

Because of its important role in state regulation of matters of health and safety, common law liability cannot be easily displaced in our federal system. *Buckman* underscored this fact, finding implied preemption of a newly-fashioned state cause of action only where (1) no presumption against federal preemption obtained, and (2) the cause of action, by assigning liability *solely* on the basis of fraud against the FDA, imposed significant and distinctive burdens on the FDA and the entities it regulates. The appeal before us presents a very different set of circumstances, one in which there is a clear presumption against preemption of long-standing common law claims. In the presence of this presumption, because Michigan law does not in fact implicate the concerns that animated the Supreme Court's decision in *Buckman*, and because Appellants' lawsuits depend primarily on traditional and preexisting tort sources, not at all on a "fraud-on-the-FDA" cause of action created by state law, and only incidentally on evidence of such fraud, we conclude that the Michigan immunity exception is not prohibited through preemption. It follows that common law liability is not foreclosed by federal law, and Appellants' claims should not have been dismissed.

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in the face of an FDA statement asserting preemption, the common law claims preserved by Michigan's immunity exception cannot be preempted by federal law absent a clear statement from Congress. In any event, since no such FDA statement dealing with Appellants' claims has been made, the question of its effect, were one to issue, is not before us.

For the foregoing reasons, we VACATE the District Court's grant of judgment on the pleadings, and we REMAND the case to the District Court for further proceedings.

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

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00 Civ. 2843 LAK
February 24, 2005 10:12 a.m.

IN RE: REZULIN

Before:

HON. LEWIS A. KAPLAN,
District Judge

APPEARANCES

RYAN M. MCNAMARA,
J. DOUGLAS PETERS,
KAREN E. KOSKOFF,
Attorneys for plaintiffs

DAVID KLINGSBERG,
WENDY S. DOWSE,
BERT L. SLONIM,
Attorneys for defendants

So far as the footnote to which plaintiffs' counsel referred, I think that while the Court of Appeals referred to the lack of evidence, as your Honor recognized when the court then went on to decide this not on the basis of evidence, but on the basis of the unconstitutionality and severance of the provision, that that all went by the boards and became irrelevant.

We suggest that, respectfully, that the motion should be granted because of the Garcia controlling authority and severing out that part of the statute, and there is no allegation and, indeed, could not be any allegation, to meet Garcia's interpretation of the Michigan statute, that there is a federal FDA finding of fraud on the FDA which was intentional and which would have led to withdrawal of the drug.

Thank you.

THE COURT: Thank you.

The argument is very helpful and I am prepared to rule now, although I reserve the right to edit the transcript so that it makes sense in writing as well as spoken English.

(Recess)

THE COURT: We deal here with 7 of the many hundreds of individual product liability actions that are consolidated for pretrial purposes before me by the Multidistrict Panel, and specifically with the claims of approximately 178 plaintiffs, each of whom ingested Rezulin and each of whom at all relevant times was a resident of Michigan.

One or more of these cases was filed in California. The rest were filed in Michigan. All were transferred here by the Multidistrict Panel. Michigan has an interesting statute which is the basis of the defendants' motion. Section 600.2946 (5) of Michigan compiled laws provides, in substance, that no drug manufacturer may

be held liable in a product liability case based on a drug if the drug was approved for safety and efficacy by the Food & Drug Administration and the drug was properly labeled.

The statute is subject to two exceptions:

First, the immunity conferred by the statute does not apply, "if the manufacturer intentionally withheld or misrepresented material information concerning the drug that is required to be submitted under the Food, Drug & Cosmetics Act, and the drug would not have been approved or the FDA would have withdrawn approval if the information was accurately submitted to the FDA; or if the manufacturer bribed an FDA official or employee to secure the drug's approval.

The second exception applies where the offending drug was sold after the FDA withdrew approval or ordered the drug removed from the market.

It is the first of these exceptions that is at issue here, as the manufacturer here moves for judgment on the pleadings, dismissing the complaints of all of the Michigan plaintiffs, including those who filed in California, and the plaintiffs seek to bring themselves within the first of the exceptions I have mentioned, which I am going to refer to by the shorthand of the fraud on the FDA exception.

The first issue is a matter of choice of law. All of the plaintiffs who are represented by counsel from Michigan or elsewhere other than California, concede that Michigan law governs. The plaintiffs who are represented by the Girardi firm in Los Angeles contend that I should apply California law; and, therefore, need not concern myself with the Michigan statute. They rely on the assertion that I am to apply under what they say are settled principles the law of the forum state even after transfer.

They've got it all wrong. In an earlier decision in this case, reported at 210 Federal Rules Decision 61, decided in 2002, I stated what the principles of law referred to actually are, whereas here a case is transferred, the transferee court applies the choice of law rules of the transferrer court.

Accordingly, with respect to those plaintiffs who filed in California, I am to apply California choice of law rules, I am to apply California substantive law if and only if under the law of California governing choice of law, California would apply its own substantive law.

There is, in fact, no serious argument for the application of California substantive law. The plaintiffs who make this argument were residents of Michigan at all relevant times. The only connection between California and those plaintiffs is the fact that they happen to hire lawyers in California who brought suit in California.

As much as I am in favor, as I indicated in argument, of lawyers making livings, that just isn't good enough. Michigan's interests on anybody's analysis outweigh California's, which are trivial. So I apply Michigan substantive law to the claims of all of the plaintiffs.

The question, therefore, is whether the plaintiffs, assuming they have adequately pled fraud on the FDA, should be afforded an opportunity to try to prove it in this court.

The starting point for this analysis, in my view, and I think everybody else's, is the Supreme Court's decision four years ago in this week, Buckman Company versus Plaintiffs' Legal Committee, 541 U.S. 341 (2001). In that case, plaintiffs brought an action or actions against a manufacturer of orthopedic bone screws, claiming that the manufacturers had committed fraud on the FDA.

They sought recovery on the ground that the manufacturer's fraud on the FDA was a breach of duty and a

cause of the injuries that the plaintiffs had suffered. Their theory was that if the FDA had been told the truth, to put it in colloquial terms, it would not have approved the bone screws, the plaintiffs wouldn't have had them implanted; and, therefore, the plaintiffs wouldn't have been injured.

In a 7-to-2 decision, the United States Supreme Court held that there could be no recovery on a theory of fraud on the FDA because the Food, Drug & Cosmetic Act preempted the matter of fraud on the FDA. It reached its conclusion after noting that allowing state law tort claims based on fraud on the FDA would, and now I quote:

"Conflict with the FDA's responsibility to police fraud consistently with the administration's judgment and objectives. As a practical matter, compliance with the FDA's detailed legislature regime in the shadow of 50 states' tort regimes will dramatically increase the burdens facing potential applicants" for FDA approval, 531 U.S., at 350.

The court indicated it might deter applicants from seeking approval of medical devices under Section 510(k) of the Food, Drug & Cosmetics Act, as amended by the Medical Devices Amendments of 1976, for fear that seeking such approval would expose them to liability.

The court relied also on its view that allowing state law tort claims based on fraud on the FDA theories could cause applicants to deluge the FDA with unwanted information to protect against state law fraud on the FDA claims.

The second piece of the puzzle is the 6th Circuit's decision in October in Garcia versus Wyeth-Ayerst Laboratories, 385 Fed 3rd. 961. The plaintiff in that case, a Michigan plaintiff who sued in Michigan, brought a

products liability suit against a drug manufacturer based on her having ingested a nonsteriodal, anti-inflammatory drug known as Duract, which allegedly had caused liver failure and led to a liver transplant in order to save the life of the plaintiff. Interestingly, as in this case, the manufacturer voluntarily had withdrawn the drug from the market by the time the case was decided.

The defendant in Garcia moved for summary judgment, dismissing the case on the basis of the Michigan statute that is at issue here. The 6th Circuit, relying on Buckman, held that the fraud on the FDA exception to the Michigan statute upon which the plaintiff in Garcia relied was impliedly preempted for the same reasons as the tort remedy at issue in Buckman was preempted.

The circuit said that to allow plaintiffs in strict products liability actions in Michigan to seek to avoid the effect of the statute by coming within the fraud on the FDA exception would conflict with the FDA's responsibility to police fraud and threaten to increase burdens on applicants seeking to avoid losing the exception, or at least it alluded to those concerns previously expressed by the Supreme Court in Buckman.

The court then went on to consider whether the legislation was severable. Although it may not have put it in precisely these terms, the issue before it was whether, given the unconstitutionality of the fraud on the FDA exception, the Michigan legislature rather would have a system in which there was blanket immunity for FDA-approved drugs, immunity in the absence of a finding by the FDA or some federal forum, anyway, of fraud or no immunity for FDA approved drugs at all.

The 6th Circuit rejected the no immunity option, and it concluded that—just give me one moment—the exception was preempted except in circumstances where there had been a finding by the FDA of fraud.

Now, there is no doubt that that outcome as a matter of social policy could perhaps be criticized by reasonable people. I assume, although I have no direct knowledge of it, the truth of what counsel for some of the plaintiffs said; namely, that the FDA simply does not go around suing people or otherwise seeking to obtain or making findings that drug manufacturers have committed fraud in the new drug application process.

The 6th Circuit's conclusion, therefore, puts plaintiffs who are subject to the Michigan statute in a pretty difficult spot. It may be that that is an undesirable outcome and it may well be that Congress and/or the Michigan legislature ought to address it, and Mr. Peters was kind enough to inform me that perhaps both are doing so. But it is, frankly, none of my affair for several reasons:

First of all, in Factors, et cetera, versus Pro Arts, Inc., 652 F.2d 278, at 283 (2d Cir. 1981), the Second Circuit has made it clear that although I am not absolutely bound by the 6th Circuit's ruling, I ought to give it quite substantial deference.

The second reason is that even apart from Factors, et cetera, I think the 6th Circuit is right in its application of Buckman in this circumstance. Indeed, I think that the case for preemption, at least to the extent that I have indicated; namely, preemption, that would foreclose the fraud on the FDA exception to the statute in the absence of a finding by the FDA or in an action brought by the FDA that a material fraud resulted in the approval of the FDA—sorry. I lost the threaded sentence.

(Record read)

THE COURT: Is even stronger than the 6th Circuit made, and I think that some of the colloquy that we had here this morning really illustrates it. If plaintiffs covered by the Michigan statute were able to litigate claims of fraud on the FDA in individual personal injury suits,

whether in state courts or in federal courts, the potential would exist for the FDA's personnel to be drawn into those controversies on a case-by-case basis over and over again.

I recognize that over time there would be a reduction in the extent to which that might occur by virtue of application of principles of collateral estoppel, res judicata, but the fact of the matter is that for some significant period of time at the beginning of every cycle of new drug litigation, the question would arise over and over again, often in all 50 states, often in every county in America, as to whether the FDA had been defrauded in the new drug application process.

The Food and Drug Administration would become the Food, Drug & Litigation Administration. The interference with the proper discharge of the mission that Congress created the FDA to perform would be enormous. It's just a wholly impractical situation, and so I, too, conclude that the exception in the Michigan statute is preempted, except where the plaintiff relies on a finding by the FDA, or in an action brought by the FDA, of material fraud in the new drug approval process absent which approval would not have been granted.

Accordingly, the defendants' motion for summary judgment on the pleadings dismissing the complaints in these actions is granted.

Now, I will always invite counsel, if I made some mistake of fact or I have overlooked some legal argument that somebody thinks I ought to address, please tell me now and I'll try to address it if I think it is appropriate. Otherwise, I am not inviting reargument, but if there is something that is going to produce a motion for reargument next week, I would like to know it now and save you the trouble.

MR. PETERS: It is a small fact. The court said 178 cases. It might be 187 cases being dismissed.

THE COURT: All right. I stand corrected, and it is plaintiffs; it is not cases, right?

MR. PETERS: Plaintiffs.

MR. KLINGSBERG: Recipients of the drug.

THE COURT: I have 7 complaints with 187 plaintiffs.

MR. PETERS: Correct.

THE COURT: All right. Well, I thank you very much. I hope, Mr. Peters, you enjoy the show up in Central Park.

MR. KLINGSBERG: There are more plaintiffs because sometimes if there is a decedent, you get relatives, 187 people who were recipients of the Rezulin.

THE COURT: That is close enough for this purpose.

(Court adjourned)

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

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00 Civ. 2843 (LAK)

In re:

REZULIN PRODUCTS LIABILITY LITIGATION
(MDL No. 1348)

This Document Relates to: 00 Civ. 5117,
01 Civ. 0050, 01 Civ. 2242, 01 Civ. 9817,
03 Civ. 3488, 04 Civ. 3957, 04 Civ. 10031

PRETRIAL ORDER NO. 355
(Michigan Plaintiffs - Motion for
Judgment on the Pleadings)

LEWIS A. KAPLAN, *District Judge.*

Defendants' motion for judgment on the pleadings dismissing the complaints [00 Civ. 2843, docket item 2798) is granted for the reasons stated on the record in open court this day.

SO ORDERED.

Dated: February 24, 2005

/s/ LEWIS A. KAPLAN
Lewis A. Kaplan
United States District Judge

[LETTERHEAD OF UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT]

Filed February 12, 2007

Date:	
Docket Number:	05-1705-cv
Short Title:	Desiano v. Warner Lambert Co.
DC Docket Number:	00-cv-2843
DC:	SDNY (NEW YORK CITY)
DC Judge:	Honorable Lewis Kaplan

At a stated term of the United States Court of Appeals for the Second Circuit, held at the Daniel Patrick Moynihan United States Courthouse, 500 Pearl Street, in the City of New York, on the 12th day of February two thousand seven.

Caesar Desiano, ET AL.,

Plaintiffs-Appellants,

—v.—

Warber-Lambert Company, ET AL.,

Defendants-Appellees.

A petition for panel rehearing and a petition for rehearing en banc having been filed herein by the Defendants-Appellees Warner-Lambert Company LLC and Pfizer Inc. Upon consideration by the panel that decided the appeal, it is Ordered that said petition for rehearing is DENIED.

It is further noted that the petition for rehearing en banc has been transmitted to the judges for the court in regular active service and to any other judge that heard the appeal and that no such judge has requested that a vote be taken thereon.

For the Court,

Thomas Asreen, Acting Clerk

By: /s/ [ILLEGIBLE] HELLER
Motion Staff Attorney

U.S. CONT. art. VI, cl. 2

This Constitution, and the Laws of the United States which shall be made in Pursuance thereof; and all Treaties made, or which shall be made, under the Authority of the United States, shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby, any Thing in the Constitution or Laws of any State to the Contrary notwithstanding.

MICH. COMP. LAWS § 600.2946

§ 600.2946. Product liability action; admissible evidence

. . .

(5) In a product liability action against a manufacturer or seller, a product that is a drug is not defective or unreasonably dangerous, and the manufacturer or seller is not liable, if the drug was approved for safety and efficacy by the United States food and drug administration, and the drug and its labeling were in compliance with the United States food and drug administration's approval at the time the drug left the control of the manufacturer or seller. However, this subsection does not apply to a drug that is sold in the United States after the effective date of an order of the United States food and drug administration to remove the drug from the market or to withdraw its approval. This subsection does not apply if the defendant at any time before the event that allegedly caused the injury does any of the following:

(a) Intentionally withholds from or misrepresents to the United States food and drug administration information concerning the drug that is required to be submitted under the federal food, drug, and cosmetic act, chapter 675, 52 Stat. 1040, 21 U.S.C. 301 to 321, 331 to 343-2, 344 to 346a, 347, 348 to 353, 355 to 360, 360b to 376, and 378 to 395, and the drug would not have been approved, or the United States food and drug administration would have withdrawn approval for the drug if the information were accurately submitted.

(b) Makes an illegal payment to an official or employee of the United States food and drug administration for the purpose of securing or maintaining approval of the drug.

21 U.S.C. § 332. Injunction proceedings

(a) Jurisdiction of courts

The district courts of the United States and the United States courts of the Territories shall have jurisdiction, for cause shown[,] to restrain violations of section 331of this title, except paragraphs (h), (i), and (j).

(b) Violation of injunction

In case of violation of an injunction or restraining order issued under this section, which also constitutes a violation of this chapter, trial shall be by the court, or, upon demand of the accused, by a jury.

21 U.S.C. § 333. Penalties

(a) Violation of section 331 of this title; second violation; intent to defraud or mislead

(1) Any person who violates a provision of section 331of this title shall be imprisoned for not more than one year or fined not more than $1,000, or both.

(2) Notwithstanding the provisions of paragraph (1), if any person commits such a violation after a conviction of him under this section has become final, or commits such a violation with the intent to defraud or mislead, such person shall be imprisoned for not more than three years or fined not more than $10,000 or both.

(b) Prescription drug market violations

(1) Notwithstanding subsection (a), any person who violates section 331(t) of this title by—

(A) knowingly importing a drug in violation of section 381(d)(1) of this title,

(B) knowingly selling, purchasing, or trading a drug or drug sample or knowingly offering to sell, purchase, or trade a drug or drug sample, in violation of section 353(c)(1) of this title,

(C) knowingly selling, purchasing, or trading a coupon, knowingly offering to sell, purchase, or trade such a coupon, or knowingly counterfeiting such a coupon, in violation of section 353(c)(2) of this title, or

(D) knowingly distributing drugs in violation of section 353(e)(2)(A) of this title, shall be imprisoned for not more than 10 years or fined not more than $250,000, or both.

(2) Any manufacturer or distributor who distributes drug samples by means other than the mail or common carrier whose representative, during the course of the representative's employment or association with that manufacturer or distributor, violated section 331(t) of this title because of a violation of section 353(c)(1) of this title or violated any State law prohibiting the sale, purchase, or trade of a drug sample subject to section 353(b) of this title or the offer to sell, purchase, or trade such a drug sample shall, upon conviction of the representative for such violation, be subject to the following civil penalties:

(A) A civil penalty of not more than $50,000 for each of the first two such violations resulting in a conviction of any representative of the manufacturer or distributor in any 10-year period.

(B) A civil penalty of not more than $1,000,000 for each violation resulting in a conviction of any representative after the second conviction in any 10-year period.

For the purposes of this paragraph, multiple convictions of one or more persons arising out of the same event or transaction, or a related series of events or transactions, shall be considered as one violation.

(3) Any manufacturer or distributor who violates section 331(t) of this title because of a failure to make a report required by section 353(d)(3)(E) of this title shall be subject to a civil penalty of not more than $100,000.

(4) (A) If a manufacturer or distributor or any representative of such manufacturer or distributor provides information leading to the institution of a criminal proceeding against, and conviction of, any representative of that manufacturer or distributor for a violation of section

331(t) of this title because of a sale, purchase, or trade or offer to purchase, sell, or trade a drug sample in violation of section 353(c)(1) of this title or for a violation of State law prohibiting the sale, purchase, or trade or offer to sell, purchase, or trade a drug sample, the conviction of such representative shall not be considered as a violation for purposes of paragraph (2).

(B) If, in an action brought under paragraph (2) against a manufacturer or distributor relating to the conviction of a representative of such manufacturer or distributor for the sale, purchase, or trade of a drug or the offer to sell, purchase, or trade a drug, it is shown, by clear and convincing evidence—

(i) that the manufacturer or distributor conducted, before the institution of a criminal proceeding against such representative for the violation which resulted in such conviction, an investigation of events or transactions which would have led to the reporting of information leading to the institution of a criminal proceeding against, and conviction of, such representative for such purchase, sale, or trade or offer to purchase, sell, or trade, or

(ii) that, except in the case of the conviction of a representative employed in a supervisory function, despite diligent implementation by the manufacturer or distributor of an independent audit and security system designed to detect such a violation, the manufacturer or distributor could not reasonably have been expected to have detected such violation,

the conviction of such representative shall not be considered as a conviction for purposes of paragraph (2).

(5) If a person provides information leading to the institution of a criminal proceeding against, and con-

viction of, a person for a violation of section 331(t) of this title because of the sale, purchase, or trade of a drug sample or the offer to sell, purchase, or trade a drug sample in violation of section 353(c)(1) of this title, such person shall be entitled to one-half of the criminal fine imposed and collected for such violation but not more than $125,000.

(6) Notwithstanding subsection (a), any person who is a manufacturer or importer of a prescription drug under section 384(b) of this title and knowingly fails to comply with a requirement of section 384(e) of this title that is applicable to such manufacturer or importer, respectively, shall be imprisoned for not more than 10 years or fined not more than $250,000, or both.

(c) Exceptions in certain cases of good faith, etc.

No person shall be subject to the penalties of subsection (a)(1) of this section, (1) for having received in interstate commerce any article and delivered it or proffered delivery of it, if such delivery or proffer was made in good faith, unless he refuses to furnish on request of an officer or employee duly designated by the Secretary the name and address of the person from whom he purchased or received such article and copies of all documents, if any there be, pertaining to the delivery of the article to him; or (2) for having violated section 331(a), (d) of this title, if he establishes a guaranty or undertaking signed by, and containing the name and address of, the person residing in the United States from whom he received in good faith the article, to the effect, in case of an alleged violation of section 331(a) of this title, that such article is not adulterated or misbranded, within the meaning of this chapter, designating this chapter, or to the effect, in case of an alleged violation of section 331(d) of this title, that such article is not an article which may not,

under the provisions of section 344 or 355 of this title, be introduced into interstate commerce; or (3) for having violated section 331(a) of this title, where the violation exists because the article is adulterated by reason of containing a color additive not from a batch certified in accordance with regulations promulgated by the Secretary, under this chapter, if such person establishes a guaranty or undertaking signed by, and containing the name and address of, the manufacturer of the color additive, to the effect that such color additive was from a batch certified in accordance with the applicable regulations promulgated by the Secretary under this chapter; or (4) for having violated section 331(b), (c) or (k) of this title by failure to comply with section 352(f) of this title in respect to an article received in interstate commerce to which neither section 353(a) of this title nor section 353(b)(1) of this title is applicable, if the delivery or proffered delivery was made in good faith and the labeling at the time thereof contained the same directions for use and warning statements as were contained in the labeling at the time of such receipt of such article; or (5) for having violated section 331(i)(2) of this title if such person acted in good faith and had no reason to believe that use of the punch, die, plate, stone, or other thing involved would result in a drug being a counterfeit drug, or for having violated section 331(i)(3) of this title if the person doing the act or causing it to be done acted in good faith and had no reason to believe that the drug was a counterfeit drug.

(d) Exceptions involving misbranded food

No person shall be subject to the penalties of subsection (a)(1) of this section for a violation of section § 331 of this title involving misbranded food if the violation

exists solely because the food is misbranded under section 343(a)(2) of this title because of its advertising.

(e) Prohibited distribution of human growth hormone

(1) Except as provided in paragraph (2), whoever knowingly distributes, or possesses with intent to distribute, human growth hormone for any use in humans other than the treatment of a disease or other recognized medical condition, where such use has been authorized by the Secretary of Health and Human Services under section 355 of this title and pursuant to the order of a physician, is guilty of an offense punishable by not more than 5 years in prison, such fines as are authorized by Title 18, or both.

(2) Whoever commits any offense set forth in paragraph (1) and such offense involves an individual under 18 years of age is punishable by not more than 10 years imprisonment, such fines as are authorized by Title 18, or both.

(3) Any conviction for a violation of paragraphs (1) and (2) of this subsection shall be considered a felony violation of the Controlled Substances Act for the purposes of forfeiture under section 413 of such Act.

(4) As used in this subsection the term "human growth hormone" means somatrem, somatropin, or an analogue of either of them.

(5) The Drug Enforcement Administration is authorized to investigate offenses punishable by this subsection.

(f) Redesignated (g)

(g) Violations related to devices

(1) (A) Except as provided in subparagraph (B), any person who violates a requirement of this chapter which relates to devices shall be liable to the United States for a civil penalty in an amount not to exceed $ 15,000 for each such violation, and not to exceed $1,000,000 for all such violations adjudicated in a single proceeding. For purposes of the preceding sentence, a person accredited under paragraph (2) of section 374(g) of this title who is substantially not in compliance with the standards of accreditation under such section, or who poses a threat to public health or fails to act in a manner that is consistent with the purposes of such section, shall be considered to have violated a requirement of this chapter that relates to devices.

(B) Subparagraph (A) shall not apply—

(i) to any person who violates the requirements of section 360i(a) or 360j(f) of this title unless such violation constitutes (I) a significant or knowing departure from such requirements, or (II) a risk to public health,

(ii) to any person who commits minor violations of section 360i(e) or (f) of this title (only with respect to correction reports) if such person demonstrates substantial compliance with such section, or

(iii) to violations of section 351(a)(2)(A) of this title which involve one or more devices which are not defective.

(2) (A) Any person who introduces into interstate commerce or delivers for introduction into interstate commerce an article of food that is adulterated within the meaning of section 342(a)(2)(B) of this title shall be subject to a civil money penalty of not more than

$50,000 in the case of an individual and $250,000 in the case of any other person for such introduction or delivery, not to exceed $500,000 for all such violations adjudicated in a single proceeding.

(B) This paragraph shall not apply to any person who grew the article of food that is adulterated. If the Secretary assesses a civil penalty against any person under this paragraph, the Secretary may not use the criminal authorities under this section to sanction such person for the introduction or delivery for introduction into interstate commerce of the article of food that is adulterated. If the Secretary assesses a civil penalty against any person under this paragraph, the Secretary may not use the seizure authorities of section § 334 of this title or the injunction authorities of section 332 of this title with respect to the article of food that is adulterated.

(C) In a hearing to assess a civil penalty under this paragraph, the presiding officer shall have the same authority with regard to compelling testimony or production of documents as a presiding officer has under section 346a(g)(2)(B) of this title. The third sentence of paragraph (3)(A) shall not apply to any investigation under this paragraph.

(3) (A) A civil penalty under paragraph (1) or (2) shall be assessed by the Secretary by an order made on the record after opportunity for a hearing provided in accordance with this subparagraph and section 554 of title 5. Before issuing such an order, the Secretary shall give written notice to the person to be assessed a civil penalty under such order of the Secretary's proposal to issue such order and provide such person an opportunity for a hearing on the order. In the course of any investigation, the Secretary may issue subpoenas requiring the atten-

dance and testimony of witnesses and the production of evidence that relates to the matter under investigation.

(B) In determining the amount of a civil penalty, the Secretary shall take into account the nature, circumstances, extent, and gravity of the violation or violations and, with respect to the violator, ability to pay, effect on ability to continue to do business, any history of prior such violations, the degree of culpability, and such other matters as justice may require.

(C) The Secretary may compromise, modify, or remit, with or without conditions, any civil penalty which may be assessed under paragraph (1) or (2). The amount of such penalty, when finally determined, or the amount agreed upon in compromise, may be deducted from any sums owing by the United States to the person charged.

(4) Any person who requested, in accordance with paragraph (3)(A), a hearing respecting the assessment of a civil penalty and who is aggrieved by an order assessing a civil penalty may file a petition for judicial review of such order with the United States Court of Appeals for the District of Columbia Circuit or for any other circuit in which such person resides or transacts business. Such a petition may only be filed within the 60-day period beginning on the date the order making such assessment was issued.

(5) If any person fails to pay an assessment of a civil penalty—

> (A) after the order making the assessment becomes final, and if such person does not file a petition for judicial review of the order in accordance with paragraph (4), or

(B) after a court in an action brought under paragraph (4) has entered a final judgment in favor of the Secretary, the Attorney General shall recover the amount assessed (plus interest at currently prevailing rates from the date of the expiration of the 60-day period referred to in paragraph (4) or the date of such final judgment, as the case may be) in an action brought in any appropriate district court of the United States. In such an action, the validity, amount, and appropriateness of such penalty shall not be subject to review.

21 U.S.C. § 334. Seizure

(a) Grounds and jurisdiction

(1) Any article of food, drug, or cosmetic that is adulterated or misbranded when introduced into or while in interstate commerce or while held for sale (whether or not the first sale) after shipment in interstate commerce, or which may not, under the provisions of section 344 or 355 of this title, be introduced into interstate commerce, shall be liable to be proceeded against while in interstate commerce, or at any time thereafter, on libel of information and condemned in any district court of the United States or United States court of a Territory within the jurisdiction of which the article is found. No libel for condemnation shall be instituted under this chapter, for any alleged misbranding if there is pending in any court a libel for condemnation proceeding under this chapter based upon the same alleged misbranding, and not more than one such proceeding shall be instituted if no such proceeding is so pending, except that such limitations shall not apply (A) when such misbranding has been the basis of a prior judgment in favor of the United States, in a criminal, injunction, or libel for condemnation proceeding under this chapter, or (B) when the Secretary has probable cause to believe from facts found, without hearing, by him or any officer or employee of the Department that the misbranded article is dangerous to health, or that the labeling of the misbranded article is fraudulent, or would be in a material respect misleading to the injury or damage of the purchaser or consumer. In any case where the number of libel for condemnation proceedings is limited as above provided the proceeding pending or instituted shall, on application of the claimant, seasonably made, be removed for trial to any district agreed upon by stipulation between the parties,

or, in case of failure to so stipulate within a reasonable time, the claimant may apply to the court of the district in which the seizure has been made, and such court (after giving the United States attorney for such district reasonable notice and opportunity to be heard) shall by order, unless good cause to the contrary is shown, specify a district of reasonable proximity to the claimant's principal place of business, to which the case shall be removed for trial.

(2) The following shall be liable to be proceeded against at any time on libel of information and condemned in any district court of the United States or United States court of a Territory within the jurisdiction of which they are found: (A) Any drug that is a counterfeit drug, (B) Any container of a counterfeit drug, (C) Any punch, die, plate, stone, labeling, container, or other thing used or designed for use in making a counterfeit drug or drugs, and (D) Any adulterated or misbranded device.

(3) (A) Except as provided in subparagraph (B), no libel for condemnation may be instituted under paragraph (1) or (2) against any food which—

(i) is misbranded under section 343(a)(2) of this title because of its advertising, and

(ii) is being held for sale to the ultimate consumer in an establishment other than an establishment owned or operated by a manufacturer, packer, or distributor of the food.

(B) A libel for condemnation may be instituted under paragraph (1) or (2) against a food described in subparagraph (A) if—

(i) (I) the food's advertising which resulted in the food being misbranded under section 403(a)(2) [21 USCS § 343(a)(2)] was disseminated in the establishment in which the food is being held for sale to the ultimate consumer,

(II) such advertising was disseminated by, or under the direction of, the owner or operator of such establishment, or

(III) all or part of the cost of such advertising was paid by such owner or operator; and

(ii) the owner or operator of such establishment used such advertising in the establishment to promote the sale of the food.

(b) Procedure; multiplicity of pending proceedings

The article, equipment, or other thing proceeded against shall be liable to seizure by process pursuant to the libel, and the procedure in cases under this section shall conform, as nearly as may be, to the procedure in admiralty; except that on demand of either party any issue of fact joined in any such case shall be tried by jury. When libel for condemnation proceedings under this section, involving the same claimant and the same issues of adulteration or misbranding, are pending in two or more jurisdictions, such pending proceedings, upon application of the claimant seasonably made to the court of one such jurisdiction, shall be consolidated for trial by order of such court, and tried in (1) any district selected by the claimant where one of such proceedings is pending; or (2) a district agreed upon by stipulation between the parties. If no order for consolidation is so made within a reasonable time, the claimant may apply to the court of one such jurisdiction, and such court (after giving the United States attorney for such district reasonable notice

and opportunity to be heard) shall by order, unless good cause to the contrary is shown, specify a district of reasonable proximity to the claimant's principal place of business, in which all such pending proceedings shall be consolidated for trial and tried. Such order of consolidation shall not apply so as to require the removal of any case the date for trial of which has been fixed. The court granting such order shall give prompt notification thereof to the other courts having jurisdiction of the cases covered thereby.

(c) Availability of samples of seized goods prior to trial

The court at any time after seizure up to a reasonable time before trial shall by order allow any party to a condemnation proceeding, his attorney or agent, to obtain a representative sample of the article seized and a true copy of the analysis, if any, on which the proceeding is based and the identifying marks or numbers, if any, of the packages from which the samples analyzed were obtained.

(d) Disposition of goods after decree of condemnation; claims for remission or mitigation of forfeitures

(1) Any food, drug, device, or cosmetic condemned under this section shall, after entry of the decree, be disposed of by destruction or sale as the court may, in accordance with the provisions of this section, direct and the proceeds thereof, if sold, less the legal costs and charges, shall be paid into the Treasury of the United States; but such article shall not be sold under such decree contrary to the provisions of this chapter or the laws of the jurisdiction in which sold. After entry of the decree and upon the payment of the costs of such proceedings and the execution of a good and sufficient bond conditioned that such article shall not be sold or dis-

posed of contrary to the provisions of this chapter or the laws of any State or Territory in which sold, the court may by order direct that such article be delivered to the owner thereof to be destroyed or brought into compliance with the provisions of this chapter under the supervision of an officer or employee duly designated by the Secretary, and the expenses of such supervision shall be paid by the person obtaining release of the article under bond. If the article was imported into the United States and the person seeking its release establishes (A) that the adulteration, misbranding, or violation did not occur after the article was imported, and (B) that he had no cause for believing that it was adulterated, misbranded, or in violation before it was released from customs custody, the court may permit the article to be delivered to the owner for exportation in lieu of destruction upon a showing by the owner that all of the conditions of section 381(e) of this title can and will be met. The provisions of this sentence shall not apply where condemnation is based upon violation of section 342(a)(1), (2), or (6) of this title, section 351(a)(3) of this title, section 352(j) of this title, or section 361(a) or (d) of this title. Where such exportation is made to the original foreign supplier, then subparagraphs (A) and (B) of section 381(e)(1)(A), (B) of this title and the preceding sentence shall not be applicable; and in all cases of exportation the bond shall be conditioned that the article shall not be sold or disposed of until the applicable conditions of section 381(e) of this title have been met. Any person seeking to export an imported article pursuant to any of the provisions of this subsection shall establish that the article was intended for export at the time the article entered commerce. Any article condemned by reason of its being an article which may not, under section § 344 or 355 of this title be introduced into

interest to commerce, shall be disposed of by destruction.

(2) The provisions of paragraph (1) of this subsection shall, to the extent deemed appropriate by the court, apply to any equipment or other thing which is not otherwise within the scope of such paragraph and which is referred to in paragraph (2) of subsection (a).

(3) Whenever in any proceeding under this section, involving paragraph (2) of subsection (a), the condemnation of any equipment or thing (other than a drug) is decreed, the court shall allow the claim of any claimant, to the extent of such claimant's interest, for remission or mitigation of such forfeiture if such claimant proves to the satisfaction of the court (i) that he has not committed or caused to be committed any prohibited act referred to in such paragraph (2) and has no interest in any drug referred to therein, (ii) that he has an interest in such equipment or other thing as owner or lienor or otherwise, acquired by him in good faith, and (iii) that he at no time had any knowledge or reason to believe that such equipment or other thing was being or would be used in, or to facilitate, the violation of laws of the United States relating to counterfeit drugs.

(e) Costs

When a decree of condemnation is entered against the article, court costs and fees, and storage and other proper expenses, shall be awarded against the person, if any, intervening as claimant of the article.

(f) Removal of case for trial

In the case of removal for trial of any case as provided by subsection (a) or (b)—

(1) The clerk of the court from which removal is made shall promptly transmit to the court in which the case is

to be tried all records in the case necessary in order that such court may exercise jurisdiction.

(2) The court to which such case was removed shall have the powers and be subject to the duties, for purposes of such case, which the court from which removal was made would have had, or to which such court would have been subject, if such case had not been removed.

(g) Administrative restraint; detention orders

(1) If during an inspection conducted under section 374 of this title of a facility or a vehicle, a device which the officer or employee making the inspection has reason to believe is adulterated or misbranded is found in such facility or vehicle, such officer or employee may order the device detained (in accordance with regulations prescribed by the Secretary) for a reasonable period which may not exceed twenty days unless the Secretary determines that a period of detention greater than twenty days is required to institute an action under subsection (a) or section 332 of this title, in which case he may authorize a detention period of not to exceed thirty days. Regulations of the Secretary prescribed under this paragraph shall require that before a device may be ordered detained under this paragraph the Secretary or an officer or employee designated by the Secretary approve such order. A detention order under this paragraph may require the labeling or marking of a device during the period of its detention for the purpose of identifying the device as detained. Any person who would be entitled to claim a device if it were seized under subsection (a) may appeal to the Secretary a detention of such device under this paragraph. Within five days of the date an appeal of a detention is filed with the Secretary, the Secretary shall after affording opportunity for an informal hearing by order confirm the detention or revoke it.

(2) (A) Except as authorized by subparagraph (B), a device subject to a detention order issued under paragraph (1) shall not be moved by any person from the place at which it is ordered detained until—

(i) released by the Secretary, or

(ii) the expiration of the detention period applicable to such order, whichever occurs first.

(B) A device subject to a detention order under paragraph (1) may be moved—

(i) in accordance with regulations prescribed by the Secretary, and

(ii) if not in final form for shipment, at the discretion of the manufacturer of the device for the purpose of completing the work required to put it in such form.

(h) Administrative detention of foods

(1) Detention authority

(A) In general

An officer or qualified employee of the Food and Drug Administration may order the detention, in accordance with this subsection, of any article of food that is found during an inspection, examination, or investigation under this Act [21 USCS §§ 301 et seq.] conducted by such officer or qualified employee, if the officer or qualified employee has credible evidence or information indicating that such article presents a threat of serious adverse health consequences or death to humans or animals.

(B) Secretary's approval

An article of food may be ordered detained under subparagraph (A) only if the Secretary or an official designated by the Secretary approves the order. An official may not be so designated unless the official is the director of the district under this chapter in which the article involved is located, or is an official senior to such director.

(2) Period of detention

An article of food may be detained under paragraph (1) for a reasonable period, not to exceed 20 days, unless a greater period, not to exceed 30 days, is necessary, to enable the Secretary to institute an action under subsection (a) or section 302 [21 USCS § 332]. The Secretary shall by regulation provide for procedures for instituting such action on an expedited basis with respect to perishable foods.

(3) Security of detained article

An order under paragraph (1) with respect to an article of food may require that such article be labeled or marked as detained, and shall require that the article be removed to a secure facility, as appropriate. An article subject to such an order shall not be transferred by any person from the place at which the article is ordered detained, or from the place to which the article is so removed, as the case may be, until released by the Secretary or until the expiration of the detention period applicable under such order, whichever occurs first. This subsection may not be construed as authorizing the delivery of the article pursuant to the execution of a bond while the article is subject to the order, and section 381(b) of this title does not autho-

rize the delivery of the article pursuant to the execution of a bond while the article is subject to the order.

(4) Appeal of detention order

(A) In general

With respect to an article of food ordered detained under paragraph (1), any person who would be entitled to be a claimant for such article if the article were seized under subsection (a) may appeal the order to the Secretary. Within five days after such an appeal is filed, the Secretary, after providing opportunity for an informal hearing, shall confirm or terminate the order involved, and such confirmation by the Secretary shall be considered a final agency action for purposes of section 702 of title 5. If during such five-day period the Secretary fails to provide such an opportunity, or to confirm or terminate such order, the order is deemed to be terminated.

(B) Effect of instituting court action

The process under subparagraph (A) for the appeal of an order under paragraph (1) terminates if the Secretary institutes an action under subsection (a) or section 332 of this title regarding the article of food involved.

21 U.S.C. § 337. Proceedings in name of United States; provision as to subpoenas

(a) Except as provided in subsection (b), all such proceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States. Subpoenas for witnesses who are required to attend a court of the United States, in any district, may run into any other district in any proceeding under this section.

. . .

21 U.S.C. § 355. New drugs

(a) Necessity of effective approval of application

No person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed pursuant to subsection (b) or (j) is effective with respect to such drug.

(b) Filing application; contents

(1) Any person may file with the Secretary an application with respect to any drug subject to the provisions of subsection (a). Such person shall submit to the Secretary as a part of the application (A) full reports of investigations which have been made to show whether or not such drug is safe for use and whether such drug is effective in use; (B) a full list of the articles used as components of such drug; (C) a full statement of the composition of such drug; (D) a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug; (E) such samples of such drug and of the articles used as components thereof as the Secretary may require; (F) specimens of the labeling proposed to be used for such drug, and (G) any assessments required under section 355c 343. The applicant shall file with the application the patent number and the expiration date of any patent which claims the drug for which the applicant submitted the application or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug. If an application is filed under this subsection for a drug and a patent which claims such drug or a method of using such drug is issued after the filing date but before approval of the application, the

applicant shall amend the application to include the information required by the preceding sentence. Upon approval of the application, the Secretary shall publish information submitted under the two preceding sentences. The Secretary shall, in consultation with the Director of the National Institutes of Health and with representatives of the drug manufacturing industry, review and develop guidance, as appropriate, on the inclusion of women and minorities in clinical trials required by clause (A).

(2) An application submitted under paragraph (1) for a drug for which the investigations described in clause (A) of such paragraph and relied upon by the applicant for approval of the application were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted shall also include—

(A) a certification, in the opinion of the applicant and to the best of his knowledge, with respect to each patent which claims the drug for which such investigations were conducted or which claims a use for such drug for which the applicant is seeking approval under this subsection and for which information is required to be filed under paragraph (1) or subsection (c)—

(i) that such patent information has not been filed,

(ii) that such patent has expired,

(iii) of the date on which such patent will expire, or

(iv) that such patent is invalid or will not be infringed by the manufacture, use, or sale of

the new drug for which the application is submitted; and

(B) if with respect to the drug for which investigations described in paragraph (1)(A) were conducted information was filed under paragraph (1) or subsection (c) for a method of use patent which does not claim a use for which the applicant is seeking approval under this subsection, a statement that the method of use patent does not claim such a use.

(3) Notice of opinion that patent is invalid or will not be infringed

(A) Agreement to give notice. An applicant that makes a certification described in paragraph (2)(A)(iv) shall include in the application a statement that the applicant will give notice as required by this paragraph.

(B) Timing of notice. An applicant that makes a certification described in paragraph (2)(A)(iv) shall give notice as required under this paragraph—

(i) if the certification is in the application, not later than 20 days after the date of the postmark on the notice with which the Secretary informs the applicant that the application has been filed; or

(ii) if the certification is in an amendment or supplement to the application, at the time at which the applicant submits the amendment or supplement, regardless of whether the applicant has already given notice with respect to another such certification contained in the application or in an amendment or supplement to the application.

(C) Recipients of notice. An applicant required under this paragraph to give notice shall give notice to—

(i) each owner of the patent that is the subject of the certification (or a representative of the owner designated to receive such a notice); and

(ii) the holder of the approved application under this subsection for the drug that is claimed by the patent or a use of which is claimed by the patent (or a representative of the holder designated to receive such a notice).

(D) Contents of notice. A notice required under this paragraph shall—

(i) state that an application that contains data from bioavailability or bioequivalence studies has been submitted under this subsection for the drug with respect to which the certification is made to obtain approval to engage in the commercial manufacture, use, or sale of the drug before the expiration of the patent referred to in the certification; and

(ii) include a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed.

(4) (A) An applicant may not amend or supplement an application referred to in paragraph (2) to seek approval of a drug that is a different drug than the drug identified in the application as submitted to the Secretary.

(B) With respect to the drug for which such an application is submitted, nothing in this subsection or sub-

section (c)(3) prohibits an applicant from amending or supplementing the application to seek approval of a different strength.

(5) (A) The Secretary shall issue guidance for the individuals who review applications submitted under paragraph (1) or under section 262 of title 42, which shall relate to promptness in conducting the review, technical excellence, lack of bias and conflict of interest, and knowledge of regulatory and scientific standards, and which shall apply equally to all individuals who review such applications.

(B) The Secretary shall meet with a sponsor of an investigation or an applicant for approval for a drug under this subsection or section 262 of title 42 if the sponsor or applicant makes a reasonable written request for a meeting for the purpose of reaching agreement on the design and size of clinical trials intended to form the primary basis of an effectiveness claim. The sponsor or applicant shall provide information necessary for discussion and agreement on the design and size of the clinical trials. Minutes of any such meeting shall be prepared by the Secretary and made available to the sponsor or applicant upon request.

(C) Any agreement regarding the parameters of the design and size of clinical trials of a new drug under this paragraph that is reached between the Secretary and a sponsor or applicant shall be reduced to writing and made part of the administrative record by the Secretary. Such agreement shall not be changed after the testing begins, except—

(i) with the written agreement of the sponsor or applicant; or

(ii) pursuant to a decision, made in accordance with subparagraph (D) by the director of the reviewing division, that a substantial scientific issue essential to determining the safety or effectiveness of the drug has been identified after the testing has begun.

(D) A decision under subparagraph (C)(ii) by the director shall be in writing and the Secretary shall provide to the sponsor or applicant an opportunity for a meeting at which the director and the sponsor or applicant will be present and at which the director will document the scientific issue involved.

(E) The written decisions of the reviewing division shall be binding upon, and may not directly or indirectly be changed by, the field or compliance division personnel unless such field or compliance division personnel demonstrate to the reviewing division why such decision should be modified.

(F) No action by the reviewing division may be delayed because of the unavailability of information from or action by field personnel unless the reviewing division determines that a delay is necessary to assure the marketing of a safe and effective drug.

(G) For purposes of this paragraph, the reviewing division is the division responsible for the review of an application for approval of a drug under this subsection or section 262 of title 42 (including all scientific and medical matters, chemistry, manu- facturing, and controls).

(c) Period for approval of application; period for, notice, and expedition of hearing; period for issuance of order

(1) Within one hundred and eighty days after the filing of an application under subsection (b), or such additional

period as may be agreed upon by the Secretary and the applicant, the Secretary shall either—

(A) approve the application if he then finds that none of the grounds for denying approval specified in subsection (d) applies, or

(B) give the applicant notice of an opportunity for a hearing before the Secretary under subsection (d) on the question whether such application is approvable. If the applicant elects to accept the opportunity for hearing by written request within thirty days after such notice, such hearing shall commence not more than ninety days after the expiration of such thirty days unless the Secretary and the applicant otherwise agree. Any such hearing shall thereafter be conducted on an expedited basis and the Secretary's order thereon shall be issued within ninety days after the date fixed by the Secretary for filing final briefs.

(2) If the patent information described in subsection (b) could not be filed with the submission of an application under subsection (b) because the application was filed before the patent information was required under subsection (b) or a patent was issued after the application was approved under such subsection, the holder of an approved application shall file with the Secretary the patent number and the expiration date of any patent which claims the drug for which the application was submitted or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug. If the holder of an approved application could not file patent information under subsection (b) because it

was not required at the time the application was approved, the holder shall file such information under this subsection not later than thirty days after the date of the enactment of this sentence, and if the holder of an approved application could not file patent information under subsection (b) because no patent had been issued when an application was filed or approved, the holder shall file such information under this subsection not later than thirty days after the date the patent involved is issued. Upon the submission of patent information under this subsection, the Secretary shall publish it.

(3) The approval of an application filed under subsection (b) which contains a certification required by paragraph (2) of such subsection shall be made effective on the last applicable date determined by applying the following to each certification made under subsection (b)(2)(A):

(A) If the applicant only made a certification described in clause (i) or (ii) of subsection (b)(2)(A) or in both such clauses, the approval may be made effective immediately.

(B) If the applicant made a certification described in clause (iii) of subsection (b)(2)(A), the approval may be made effective on the date certified under clause (iii).

(C) If the applicant made a certification described in clause (iv) of subsection (b)(2)(A), the approval shall be made effective immediately unless, before the expiration of 45 days after the date on which the notice described in subsection (b)(3) is received, an action is brought for infringement of the patent that is the subject of the certification and for which information was submitted to the Secretary under

paragraph (2) or subsection (b)(1) before the date on which the application (excluding an amendment or supplement to the application) was submitted. If such an action is brought before the expiration of such days, the approval may be made effective upon the expiration of the thirty-month period beginning on the date of the receipt of the notice provided under subsection (b)(3) or such shorter or longer period as the court may order because either party to the action failed to reasonably cooperate in expediting the action, except that—

(i) if before the expiration of such period the district court decides that the patent is invalid or not infringed (including any substantive determination that there is no cause of action for patent infringement or invalidity), the approval shall be made effective on—

(I) the date on which the court enters judgment reflecting the decision; or

(II) the date of a settlement order or consent decree signed and entered by the court stating that the patent that is the subject of the certification is invalid or not infringed;

(ii) if before the expiration of such period the district court decides that the patent has been infringed—

(I) if the judgment of the district court is appealed, the approval shall be made effective on—

(aa) the date on which the court of appeals decides that the patent is invalid or not infringed (including any

substantive determination that there is no cause of action for patent infringement or invalidity); or

(bb) the date of a settlement order or consent decree signed and entered by the court of appeals stating that the patent that is the subject of the certification is invalid or not infringed; or

(II) if the judgment of the district court is not appealed or is affirmed, the approval shall be made effective on the date specified by the district court in a court order under section 271(e)(4)(A) of title 35;

(iii) if before the expiration of such period the court grants a preliminary injunction prohibiting the applicant from engaging in the commercial manufacture or sale of the drug until the court decides the issues of patent validity and infringement and if the court decides that such patent is invalid or not infringed, the approval shall be made effective as provided in clause (i);

(iv) if before the expiration of such period the court grants a preliminary injunction prohibiting the applicant from engaging in the commercial manufacture or sale of the drug until the court decides the issues of patent validity and infringement and if the court decides that such patent has been infringed, the approval shall be made effective as provided in clause (ii).

In such an action, each of the parties shall reasonably cooperate in expediting the action.

(D) Civil action to obtain patent certainty

(i) Declaratory judgment absent infringement action

(I) In general

No action may be brought under section 2201 of title 28, by an applicant referred to in subsection (b)(2) for a declaratory judgment with respect to a patent which is the subject of the certification referred to in subparagraph (C) unless—

(aa) the 45-day period referred to in such subparagraph has expired;

(bb) neither the owner of such patent nor the holder of the approved application under subsection (b) for the drug that is claimed by the patent or a use of which is claimed by the patent brought a civil action against the applicant for infringement of the patent before the expiration of

(cc) in any case in which the notice provided under paragraph (2)(B) relates to noninfringement, the notice was accompanied by a document described in subclause (III).

(II) Filing of civil action. If the conditions described in items (aa), (bb), and as applicable, (cc) of subclause (I) have

been met, the applicant referred to in such subclause may, in accordance with section 2201 of title 28, bring a civil action under such section against the owner or holder referred to in such subclause (but not against any owner or holder that has brought such a civil action against the applicant, unless that civil action was dismissed without prejudice) for a declaratory judgment that the patent is invalid or will not be infringed by the drug for which the applicant seeks approval, except that such civil action may be brought for a declaratory judgment that the patent will not be infringed only in a case in which the condition described in subclause (I)(cc) is applicable. A civil action referred to in this subclause shall be brought in the judicial district where the defendant has its principal place of business or a regular and established place of business.

(III) Offer of confidential access to application. For purposes of subclause (I)(cc), the document described in this subclause is a document providing an offer of confidential access to the application that is in the custody of the applicant referred to in subsection (b)(2) for the purpose of determining whether an action referred to in subparagraph (C) should be brought. The document providing the offer of confidential access shall contain such restrictions as to per-

sons entitled to access, and on the use and disposition of any information accessed, as would apply had a protective order been entered for the purpose of protecting trade secrets and other confidential business information. A request for access to an application under an offer of confidential access shall be considered acceptance of the offer of confidential access with the restrictions as to persons entitled to access, and on the use and disposition of any information accessed, contained in the offer of confidential access, and those restrictions and other terms of the offer of confidential access shall be considered terms of an enforceable contract. Any person provided an offer of confidential access shall review the application for the sole and limited purpose of evaluating possible infringement of the patent that is the subject of the certification under subsection (b)(2)(A)(iv) and for no other purpose, and may not disclose information of no relevance to any issue of patent infringement to any person other than a person provided an offer of confidential access. Further, the application may be redacted by the applicant to remove any information of no relevance to any issue of patent infringement.

(ii) Counterclaim to infringement action

(I) In general

If an owner of the patent or the holder of the approved application under subsection (b) for the drug that is claimed by the patent or a use of which is claimed by the patent brings a patent infringement action against the applicant, the applicant may assert a counterclaim seeking an order requiring the holder to correct or delete the patent information submitted by the holder under subsection (b) or this subsection on the ground that the patent does not claim either—

(aa) the drug for which the application was approved; or

(bb) an approved method of using the drug.

(II) No independent cause of action. Subclause (I) does not authorize the assertion of a claim described in subclause (I) in any civil action or proceeding other than a counterclaim described in subclause (I).

(iii) No damages

An applicant shall not be entitled to damages in a civil action under clause (i) or a counterclaim under clause (ii).

(E) (i) If an application (other than an abbreviated new drug application) submitted under subsection (b) for a drug, no active ingredient (including any

ester or salt of the active ingredient) of which has been approved in any other application under subsection (b), was approved during the period beginning January 1, 1982, and ending on September 24, 1984, the Secretary may not make the approval of another application for a drug for which the investigations described in clause (A) of subsection (b)(1) and relied upon by the applicant for approval of the application were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted effective before the expiration of ten years from the date of the approval of the application previously approved under subsection (b).

(ii) If an application submitted under subsection (b) for a drug, no active ingredient (including any ester or salt of the active ingredient) of which has been approved in any other application under subsection (b), is approved after September 24, 1984, no application which refers to the drug for which the subsection (b) application was submitted and for which the investigations described in clause (A) of subsection (b)(1) and relied upon by the applicant for approval of the application were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted may be submitted under subsection (b) before the expiration of five years from the date of the approval of the application under subsection (b), except that such an application may be submitted under subsection (b) after the expiration of four years from the date of the approval of the subsection (b) application if it contains a certification of

patent invalidity or noninfringement described in clause (iv) of subsection (b)(2)(A). The approval of such an application shall be made effective in accordance with this paragraph except that, if an action for patent infringement is commenced during the one-year period beginning forty-eight months after the date of the approval of the subsection (b) application, the thirty-month period referred to in subparagraph (C) shall be extended by such amount of time (if any) which is required for seven and one-half years to have elapsed from the date of approval of the subsection (b) application.

(iii) If an application submitted under subsection (b) for a drug, which includes an active ingredient (including any ester or salt of the active ingredient) that has been approved in another application approved under subsection (b), is approved after September 24, 1984, and if such application contains reports of new clinical investigations (other than bioavailability studies) essential to the approval of the application and conducted or sponsored by the applicant, the Secretary may not make the approval of an application submitted under subsection (b) for the conditions of approval of such drug in the approved subsection (b) application effective before the expiration of three years from the date of the approval of the application under subsection (b) if the investigations described in clause (A) of subsection (b)(1) and relied upon by the applicant for approval of the application were not conducted by or for the applicant and if the applicant has not obtained a right of reference or use from the person by or

(iv) If a supplement to an application approved under subsection (b) is approved after September 24, 1984 and the supplement contains reports of new clinical investigations (other than bioavailabilty [bioavailability] studies) essential to the approval of the supplement and conducted or sponsored by the person submitting the supplement, the Secretary may not make the approval of an application submitted under subsection (b) for a change approved in the supplement effective before the expiration of three years from the date of the approval of the supplement under subsection (b) if the investigations described in clause (A) of subsection (b)(1) and relied upon by the applicant for approval of the application were not conducted by or for the applicant and if the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted.

(v) If an application (or supplement to an application) submitted under subsection (b) for a drug, which includes an active ingredient (including any ester or salt of the active ingredient) that has been approved in another application under subsection (b), was approved during the period beginning January 1, 1982, and ending on September 24, 1984, the Secretary may not make the approval of an application submitted under this subsection and for which the investigations described in clause (A) of subsection (b)(1) and relied upon by the applicant for approval of the application were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted and which refers to the drug for which the subsection (b) application was submitted effective

before the expiration of two years from September 24, 1984.

(4) A drug manufactured in a pilot or other small facility may be used to demonstrate the safety and effectiveness of the drug and to obtain approval for the drug prior to manufacture of the drug in a larger facility, unless the Secretary makes a determination that a full scale production facility is necessary to ensure the safety or effectiveness of the drug.

(d) Grounds for refusing application; approval of application; "substantial evidence" defined

If the Secretary finds, after due notice to the applicant in accordance with subsection (c) and giving him an opportunity for a hearing, in accordance with said subsection, that (1) the investigations, reports of which are required to be submitted to the Secretary pursuant to subsection (b), do not include adequate tests by all methods reasonably applicable to show whether or not such drug is safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling thereof; (2) the results of such tests show that such drug is unsafe for use under such conditions or do not show that such drug is safe for use under such conditions; (3) the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug are inadequate to preserve its identity, strength, quality, and purity; (4) upon the basis of the information submitted to him as part of the application, or upon the basis of any other information before him with respect to such drug, he has insufficient information to determine whether such drug is safe for use under such conditions; or (5) evaluated on the basis of the information submitted to him as part of the application and any other information

before him with respect to such drug, there is a lack of substantial evidence that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof; or (6) the application failed to contain the patent information prescribed by subsection (b); or (7) based on a fair evaluation of all material facts, such labeling is false or misleading in any particular; he shall issue an order refusing to approve the application. If, after such notice and opportunity for hearing, the Secretary finds that clauses (1) through (6) do not apply, he shall issue an order approving the application. As used in this subsection and subsection (e), the term "substantial evidence" means evidence consisting of adequate and well-controlled investigations, including clinical investigations, by experts qualified by scientific training and experience to evaluate the effectiveness of the drug involved, on the basis of which it could fairly and responsibly be concluded by such experts that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling or proposed labeling thereof. If the Secretary determines, based on relevant science, that data from one adequate and well-controlled clinical investigation and confirmatory evidence (obtained prior to or after such investigation) are sufficient to establish effectiveness, the Secretary may consider such data and evidence to constitute substantial evidence for purposes of the preceding sentence.

(e) Withdrawal of approval; grounds; immediate suspension upon finding imminent hazard to public health

The Secretary shall, after due notice and opportunity for hearing to the applicant, withdraw approval of an application with respect to any drug under this section if the

Secretary finds (1) that clinical or other experience, tests, or other scientific data show that such drug is unsafe for use under the conditions of use upon the basis of which the application was approved; (2) that new evidence of clinical experience, not contained in such application or not available to the Secretary until after such application was approved, or tests by new methods, or tests by methods not deemed reasonably applicable when such application was approved, evaluated together with the evidence available to the Secretary when the application was approved, shows that such drug is not shown to be safe for use under the conditions of use upon the basis of which the application was approved; or (3) on the basis of new information before him with respect to such drug, evaluated together with the evidence available to him when the application was approved, that there is a lack of substantial evidence that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling thereof; or (4) the patent information prescribed by subsection (c) was not filed within thirty days after the receipt of written notice from the Secretary specifying the failure to file such information; or (5) that the application contains any untrue statement of a material fact: *Provided*, That if the Secretary (or in his absence the officer acting as Secretary) finds that there is an imminent hazard to the public health, he may suspend the approval of such application immediately, and give the applicant prompt notice of his action and afford the applicant the opportunity for an expedited hearing under this subsection; but the authority conferred by this proviso to suspend the approval of an application shall not be delegated. The Secretary may also, after due notice and opportunity for hearing to the applicant, withdraw the approval of an application sub-

mitted under subsection (b) or (j) with respect to any drug under this section if the Secretary finds (1) that the applicant has failed to establish a system for maintaining required records, or has repeatedly or deliberately failed to maintain such records or to make required reports, in accordance with a regulation or order under subsection (k) or to comply with the notice requirements of section 360(k)(2) of this title, or the applicant has refused to permit access to, or copying or verification of, such records as required by paragraph (2) of such subsection; or (2) that on the basis of new information before him, evaluated together with the evidence before him when the application was approved, the methods used in, or the facilities and controls used for, the manufacture, processing, and packing of such drug are inadequate to assure and preserve its identity, strength, quality, and purity and were not made adequate within a reasonable time after receipt of written notice from the Secretary specifying the matter complained of; or (3) that on the basis of new information before him, evaluated together with the evidence before him when the application was approved, the labeling of such drug, based on a fair evaluation of all material facts, is false or misleading in any particular and was not corrected within a reasonable time after receipt of written notice from the Secretary specifying the matter complained of. Any order under this subsection shall state the findings upon which it is based.

(f) Revocation of order refusing, withdrawing or suspending approval of application

Whenever the Secretary finds that the facts so require, he shall revoke any previous order under subsection (d) or (e) refusing, withdrawing, or suspending approval of an application and shall approve such application or reinstate such approval, as may be appropriate.

(g) Service of orders

Orders of the Secretary issued under this section shall be served (1) in person by any officer or employee of the department designated by the Secretary or (2) by mailing the order by registered mail or by certified mail addressed to the applicant or respondent at his last-known address in the records of the Secretary.

(h) Appeal from order

An appeal may be taken by the applicant from an order of the Secretary refusing or withdrawing approval of an application under this section. Such appeal shall be taken by filing in the United States court of appeals for the circuit wherein such applicant resides or has his principal place of business, or in the United States Court of Appeals for the District of Columbia Circuit, within sixty days after the entry of such order, a written petition praying that the order of the Secretary be set aside. A copy of such petition shall be forthwith transmitted by the clerk of the court to the Secretary, or any officer designated by him for that purpose, and thereupon the Secretary shall certify and file in the court the record upon which the order complained of was entered, as provided in section 2112 of title 28. Upon the filing of such petition such court shall have exclusive jurisdiction to affirm or set aside such order, except that until the filing of the record the Secretary may modify or set aside his order. No objection to the order of the Secretary shall be considered by the court unless such objection shall have been urged before the Secretary or unless there were reasonable grounds for failure so to do. The finding of the Secretary as to the facts, if supported by substantial evidence, shall be conclusive. If any person shall apply to the court for leave to adduce additional evidence, and shall show to the satisfaction of the court that such addi-

tional evidence is material and that there were reasonable grounds for failure to adduce such evidence in the proceeding before the Secretary, the court may order such additional evidence to be taken before the Secretary and to be adduced upon the hearing in such manner and upon such terms and conditions as to the court may seem proper. The Secretary may modify his findings as to the facts by reason of the additional evidence so taken, and he shall file with the court such modified findings which, if supported by substantial evidence, shall be conclusive, and his recommendation, if any, for the setting aside of the original order. The judgment of the court affirming or setting aside any such order of the Secretary shall be final, subject to review by the Supreme Court of the United States upon certiorari or certification as provided in section 1254 of title 28. The commencement of proceedings under this subsection shall not, unless specifically ordered by the court to the contrary, operate as a stay of the Secretary's order.

(i) Exemptions of drugs for research; discretionary and mandatory conditions; direct reports to Secretary

(1) The Secretary shall promulgate regulations for exempting from the operation of the foregoing subsections of this section drugs intended solely for investigational use by experts qualified by scientific training and experience to investigate the safety and effectiveness of drugs. Such regulations may, within the discretion of the Secretary, among other conditions relating to the protection of the public health, provide for conditioning such exemption upon—

(A) the submission to the Secretary, before any clinical testing of a new drug is undertaken, of reports, by the manufacturer or the sponsor of the investigation of such drug, of preclinical tests

(including tests on animals) of such drug adequate to justify the proposed clinical testing;

(B) the manufacturer or the sponsor of the investigation of a new drug proposed to be distributed to investigators for clinical testing obtaining a signed agreement from each of such investigators that patients to whom the drug is administered will be under his personal supervision, or under the supervision of investigators responsible to him, and that he will not supply such drug to any other investigator, or to clinics, for administration to human beings;

(C) the establishment and maintenance of such records, and the making of such reports to the Secretary, by the manufacturer or the sponsor of the investigation of such drug, of data (including but not limited to analytical reports by investigators) obtained as the result of such investigational use of such drug, as the Secretary finds will enable him to evaluate the safety and effectiveness of such drug in the event of the filing of an application pursuant to subsection (b); and

(D) the submission to the Secretary by the manufacturer or the sponsor of the investigation of a new drug of a statement of intent regarding whether the manufacturer or sponsor has plans for assessing pediatric safety and efficacy.

(2) Subject to paragraph (3), a clinical investigation of a new drug may begin 30 days after the Secretary has received from the manufacturer or sponsor of the investigation a submission containing such information about the drug and the clinical investigation, including—

(A) information on design of the investigation and adequate reports of basic information, certified by the applicant to be accurate reports, necessary to assess the safety of the drug for use in clinical investigation; and

(B) adequate information on the chemistry and manufacturing of the drug, controls available for the drug, and primary data tabulations from animal or human studies.

(3) (A) At any time, the Secretary may prohibit the sponsor of an investigation from conducting the investigation (referred to in this paragraph as a "clinical hold") if the Secretary makes a determination described in subparagraph (B). The Secretary shall specify the basis for the clinical hold, including the specific information available to the Secretary which served as the basis for such clinical hold, and confirm such determination in writing.

(B) For purposes of subparagraph (A), a determination described in this subparagraph with respect to a clinical hold is that—

(i) the drug involved represents an unreasonable risk to the safety of the persons who are the subjects of the clinical investigation, taking into account the qualifications of the clinical investigators, information about the drug, the design of the clinical investigation, the condition for which the drug is to be investigated, and the health status of the subjects involved; or

(ii) the clinical hold should be issued for such other reasons as the Secretary may by regulation establish (including reasons established by regulation before November 21, 1997).

(C) Any written request to the Secretary from the sponsor of an investigation that a clinical hold be removed shall receive a decision, in writing and specifying the reasons therefor, within 30 days after receipt of such request. Any such request shall include sufficient information to support the removal of such clinical hold.

(4) Regulations under paragraph (1) shall provide that such exemption shall be conditioned upon the manufacturer, or the sponsor of the investigation, requiring that experts using such drugs for investigational purposes certify to such manufacturer or sponsor that they will inform any human beings to whom such drugs, or any controls used in connection therewith, are being administered, or their representatives, that such drugs are being used for investigational purposes and will obtain the consent of such human beings or their representatives, except where it is not feasible or it is contrary to the best interests of such human beings. Nothing in this subsection shall be construed to require any clinical investigator to submit directly to the Secretary reports on the investigational use of drugs.

(j) Abbreviated new drug applications

(1) Any person may file with the Secretary an abbreviated application for the approval of a new drug.

(2) (A) An abbreviated application for a new drug shall contain—

(i) information to show that the conditions of use prescribed, recommended, or suggested in the labeling proposed for the new drug have been previously approved for a drug listed under paragraph (7) (hereinafter in this subsection referred to as a "listed drug");

(ii) (I) if the listed drug referred to in clause (i) has only one active ingredient, information to show that the active ingredient of the new drug is the same as that of the listed drug;

(II) if the listed drug referred to in clause (i) has more than one active ingredient, information to show that the active ingredients of the new drug are the same as those of the listed drug, or

(III) if the listed drug referred to in clause (i) has more than one active ingredient and if one of the active ingredients of the new drug is different and the application is filed pursuant to the approval of a petition filed under subparagraph (C), information to show that the other active ingredients of the new drug are the same as the active ingredients of the listed drug, information to show that the different active ingredient is an active ingredient of a listed drug or of a drug which does not meet the requirements of section 321(p) of this title, and such other information respecting the different active ingredient with respect to which the petition was filed as the Secretary may require;

(iii) information to show that the route of administration, the dosage form, and the strength of the new drug are the same as those of the listed drug referred to in clause (i) or, if the route of administration, the dosage form, or the strength of the new drug is different and the application is filed pursuant to the approval of a petition filed under subparagraph (C), such information respecting the route of administration, dosage form, or strength with respect to which the petition was filed as the Secretary may require;

(iv) information to show that the new drug is bioequivalent to the listed drug referred to in clause (i), except that if the application is filed pursuant to the approval of a petition filed under subparagraph (C), information to show that the active ingredients of the new drug are of the same pharmacological or therapeutic class as those of the listed drug referred to in clause (i) and the new drug can be expected to have the same therapeutic effect as the listed drug when administered to patients for a condition of use referred to in clause (i);

(v) information to show that the labeling proposed for the new drug is the same as the labeling approved for the listed drug referred to in clause (i) except for changes required because of differences approved under a petition filed under subparagraph (C) or because the new drug and the listed drug are produced or distributed by different manufacturers;

(vi) the items specified in clauses (B) through (F) of subsection (b)(1);

(vii) a certification, in the opinion of the applicant and to the best of his knowledge, with respect to each patent which claims the listed drug referred to in clause (i) or which claims a use for such listed drug for which the applicant is seeking approval under this subsection and for which information is required to be filed under subsection (b) or (c)—

(I) that such patent information has not been filed,

(II) that such patent has expired,

(III) of the date on which such patent will expire, or

(IV) that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted; and

(viii) if with respect to the listed drug referred to in clause (i) information was filed under subsection (b) or (c) for a method of use patent which does not claim a use for which the applicant is seeking approval under this subsection, a statement that the method of use patent does not claim such a use.

The Secretary may not require that an abbreviated application contain information in addition to that required by clauses (i) through (viii).

(B) Notice of opinion that patent is invalid or will not be infringed

(i) Agreement to give notice

An applicant that makes a certification described in subparagraph (A)(vii)(IV) shall include in the application a statement that the applicant will give notice as required by this subparagraph.

(ii) Timing of notice

An applicant that makes a certification described in subparagraph (A)(vii)(IV) shall give notice as required under this subparagraph—

(I) if the certification is in the application, not later than 20 days after the date of the postmark on the notice with which the Secretary informs the applicant that the application has been filed; or

(II) if the certification is in an amendment or supplement to the application, at the time at which the applicant submits the amendment or supplement, regardless of whether the applicant has already given notice with respect to another such certification contained in the application or in an amendment or supplement to the application.

(iii) Recipients of notice

An applicant required under this subparagraph to give notice shall give notice to—

(I) each owner of the patent that is the subject of the certification (or a representative of the owner designated to receive such a notice); and

(II) the holder of the approved application under subsection (b) for the drug that is claimed by the patent or a use of which is claimed by the patent (or a representative of the holder designated to receive such a notice).

(iv) Contents of notice

A notice required under this subparagraph shall—

(I) state that an application that contains data from bioavailability or bioequivalence studies has been submitted under this subsection for the drug with respect to which the certification is made to obtain approval to engage in the commercial manufacture,

use, or sale of the drug before the expiration of the patent referred to in the certification; and

(II) include a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed.

(C) If a person wants to submit an abbreviated application for a new drug which has a different active ingredient or whose route of administration, dosage form, or strength differ from that of a listed drug, such person shall submit a petition to the Secretary seeking permission to file such an application. The Secretary shall approve or disapprove a petition submitted under this subparagraph within ninety days of the date the petition is submitted. The Secretary shall approve such a petition unless the Secretary finds—

(i) that investigations must be conducted to show the safety and effectiveness of the drug or of any of its active ingredients, the route of administration, the dosage form, or strength which differ from the listed drug; or

(ii) that any drug with a different active ingredient may not be adequately evaluated for approval as safe and effective on the basis of the information required to be submitted in an abbreviated application.

(D) (i) An applicant may not amend or supplement an application to seek approval of a drug referring to a different listed drug from the listed drug identified in the application as submitted to the Secretary.

(ii) With respect to the drug for which an application is submitted, nothing in this subsection prohibits an applicant from amending or supplementing the application to seek approval of a different strength.

(iii) Within 60 days after December 8, 2003, the Secretary shall issue guidance defining the term "listed drug" for purposes of this subparagraph.

(3) (A) The Secretary shall issue guidance for the individuals who review applications submitted under paragraph (1), which shall relate to promptness in conducting the review, technical excellence, lack of bias and conflict of interest, and knowledge of regulatory and scientific standards, and which shall apply equally to all individuals who review such applications.

(B) The Secretary shall meet with a sponsor of an investigation or an applicant for approval for a drug under this subsection if the sponsor or applicant makes a reasonable written request for a meeting for the purpose of reaching agreement on the design and size of bioavailability and bioequivalence studies needed for approval of such application. The sponsor or applicant shall provide information necessary for discussion and agreement on the design and size of such studies. Minutes of any such meeting shall be prepared by the Secretary and made available to the sponsor or applicant.

(C) Any agreement regarding the parameters of design and size of bioavailability and bioequivalence studies of a drug under this paragraph that is reached between the Secretary and a sponsor or applicant shall be reduced to writing and made part

of the administrative record by the Secretary. Such agreement shall not be changed after the testing begins, except—

(i) with the written agreement of the sponsor or applicant; or

(ii) pursuant to a decision, made in accordance with subparagraph (D) by the director of the reviewing division, that a substantial scientific issue essential to determining the safety or effectiveness of the drug has been identified after the testing has begun.

(D) A decision under subparagraph (C)(ii) by the director shall be in writing and the Secretary shall provide to the sponsor or applicant an opportunity for a meeting at which the director and the sponsor or applicant will be present and at which the director will document the scientific issue involved.

(E) The written decisions of the reviewing division shall be binding upon, and may not directly or indirectly be changed by, the field or compliance office personnel unless such field or compliance office personnel demonstrate to the reviewing division why such decision should be modified.

(F) No action by the reviewing division may be delayed because of the unavailability of information from or action by field personnel unless the reviewing division determines that a delay is necessary to assure the marketing of a safe and effective drug.

(G) For purposes of this paragraph, the reviewing division is the division responsible for the review of an application for approval of a drug under this subsection (including scientific matters, chemistry, manufacturing, and controls).

(4) Subject to paragraph (5), the Secretary shall approve an application for a drug unless the Secretary finds—

(A) the methods used in, or the facilities and controls used for, the manufacture, processing, and packing of the drug are inadequate to assure and preserve its identity, strength, quality, and purity;

(B) information submitted with the application is insufficient to show that each of the proposed conditions of use have been previously approved for the listed drug referred to in the application;

(C) (i) if the listed drug has only one active ingredient, information submitted with the application is insufficient to show that the active ingredient is the same as that of the listed drug;

(ii) if the listed drug has more than one active ingredient, information submitted with the application is insufficient to show that the active ingredients are the same as the active ingredients of the listed drug, or

(iii) if the listed drug has more than one active ingredient and if the application is for a drug which has an active ingredient different from the listed drug, information submitted with the application is insufficient to show—

(I) that the other active ingredients are the same as the active ingredients of the listed drug, or

(II) that the different active ingredient is an active ingredient of a listed drug or a drug which does not meet the requirements of section 321(p) of this title or no petition

to file an application for the drug with the different ingredient was approved under paragraph (2)(C);

(D) (i) if the application is for a drug whose route of administration, dosage form, or strength of the drug is the same as the route of administration, dosage form, or strength of the listed drug referred to in the application, information submitted in the application is insufficient to show that the route of administration, dosage form, or strength is the same as that of the listed drug, or

(ii) if the application is for a drug whose route of administration, dosage form, or strength of the drug is different from that of the listed drug referred to in the application, no petition to file an application for the drug with the different route of administration, dosage form, or strength was approved under paragraph (2)(C);

(E) if the application was filed pursuant to the approval of a petition under paragraph (2)(C), the application did not contain the information required by the Secretary respecting the active ingredient, route of administration, dosage form, or strength which is not the same;

(F) information submitted in the application is insufficient to show that the drug is bioequivalent to the listed drug referred to in the application or, if the application was filed pursuant to a petition approved under paragraph (2)(C), information submitted in the application is insufficient to show that the active ingredients of the new drug are of the same pharmacological or therapeutic class as those

of the listed drug referred to in paragraph (2)(A)(i) and that the new drug can be expected to have the same therapeutic effect as the listed drug when administered to patients for a condition of use referred to in such paragraph;

(G) information submitted in the application is insufficient to show that the labeling proposed for the drug is the same as the labeling approved for the listed drug referred to in the application except for changes required because of differences approved under a petition filed under paragraph (2)(C) or because the drug and the listed drug are produced or distributed by different manufacturers;

(H) information submitted in the application or any other information available to the Secretary shows that (i) the inactive ingredients of the drug are unsafe for use under the conditions prescribed, recommended, or suggested in the labeling proposed for the drug, or (ii) the composition of the drug is unsafe under such conditions because of the type or quantity of inactive ingredients included or the manner in which the inactive ingredients are included;

(I) the approval under subsection (c) of the listed drug referred to in the application under this subsection has been withdrawn or suspended for grounds described in the first sentence of subsection (e), the Secretary has published a notice of opportunity for hearing to withdraw approval of the listed drug under subsection (c) for grounds described in the first sentence of subsection (e), the approval under this subsection of the listed drug referred to in the application under this subsection has been withdrawn or suspended under paragraph (6), or the Secretary has determined that the listed drug has

been withdrawn from sale for safety or effectiveness reasons;

(J) the application does not meet any other requirement of paragraph (2)(A); or (K) the application contains an untrue statement of material fact.

(5) (A) Within one hundred and eighty days of the initial receipt of an application under paragraph (2) or within such additional period as may be agreed upon by the Secretary and the applicant, the Secretary shall approve or disapprove the application.

(B) The approval of an application submitted under paragraph (2) shall made effective on the last applicable date determined by applying the following to each certification made under paragraph (2)(A)(vii):

(i) If the applicant only made a certification described in subclause (I) or (II) of paragraph (2)(A)(vii) or in both such subclauses, the approval may be made effective immediately.

(ii) If the applicant made a certification described in subclause (III) of paragraph (2)(A)(vii), the approval may be made effective on the date certified under subclause (III).

(iii) If the applicant made a certification described in subclause (IV) of paragraph (2)(A)(vii), the approval shall be made effective immediately unless, before the expiration of 45 days after the date on which the notice described in paragraph (2)(B) is received, an action is brought for infringement of the patent that is the subject of the certification and for which information was submitted to the Sec-

retary under subsection (b)(1) or (c)(2) before the date on which the application (excluding an amendment or supplement to the application), which the Secretary later determines to be substantially complete, was submitted. If such an action is brought before the expiration of such days, the approval shall be made effective upon the expiration of the thirty-month period beginning on the date of the receipt of the notice provided under paragraph (2)(B)(i) or such shorter or longer period as the court may order because either party to the action failed to reasonably cooperate in expediting the action, except that—

(I) if before the expiration of such period the district court decides that the patent is invalid or not infringed (including any substantive determination that there is no cause of action for patent infringement or invalidity), the approval shall be made effective on—

(aa) the date on which the court enters judgment reflecting the decision; or

(bb) the date of a settlement order or consent decree signed and entered by the court stating that the patent that is the subject of the certification is invalid or not infringed;

(II) if before the expiration of such period the district court decides that the patent has been infringed—

(aa) if the judgment of the district court is appealed, the approval shall be made effective on—

(AA) the date on which the court of appeals decides that the patent is invalid or not infringed (including any substantive determination that there is no cause of action for patent infringement or invalidity); or

(BB) the date of a settlement order or consent decree signed and entered by the court of appeals stating that the patent that is the subject of the certification is invalid or not infringed; or

(bb) if the judgment of the district court is not appealed or is affirmed, the approval shall be made effective on the date specified by the district court in a court order under section 271(e)(4)(A) of title 35;

(III) if before the expiration of such period the court grants a preliminary injunction prohibiting the applicant from engaging in the commercial manufacture or sale of the drug until the court decides the issues of patent validity and infringement and if the court decides that such patent is invalid or not infringed, the approval shall be made effective as provided in subclause (I); or

(IV) if before the expiration of such period the court grants a preliminary injunction pro-

hibiting the applicant from engaging in the commercial manufacture or sale of the drug until the court decides the issues of patent validity and infringement and if the court decides that such patent has been infringed, the approval shall be made effective as provided in subclause (II).

In such an action, each of the parties shall reasonably cooperate in expediting the action.

(iv) 180-day exclusivity period

(I) Effectiveness of application

Subject to subparagraph (D), if the application contains a certification described in paragraph (2)(A)(vii)(IV) and is for a drug for which a first applicant has submitted an application containing such a certification, the application shall be made effective on the date that is 180 days after the date of the first commercial marketing of the drug (including the commercial marketing of the listed drug) by any first applicant.

(II) Definitions

In this paragraph:

(aa) 180-day exclusivity period

The term "180-day exclusivity period" means the 180-day period ending on the day before the date on which an application submitted by an applicant other than a first applicant could become effective under this clause.

(bb) First applicant

As used in this subsection, the term "first applicant" means an applicant that, on the first day on which a substantially complete application containing a certification described in paragraph (2)(A)(vii)(IV) is submitted for approval of a drug, submits a substantially complete application that contains and lawfully maintains a certification described in paragraph (2)(A)(vii)(IV) for the drug.

(cc) Substantially complete application

As used in this subsection, the term "substantially complete application" means an application under this subsection that on its face is sufficiently complete to permit a substantive review and contains all the information required by paragraph (2)(A).

(dd) Tentative approval

(AA) In general

The term "tentative approval" means notification to an applicant by the Secretary that an application under this subsection meets the requirements of paragraph (2)(A), but cannot receive effective approval because the application does not meet the requirements of this subparagraph, there is a period of exclusivity for the listed drug

under subparagraph (F) or section 355a of this title or there is a 7-year period of exclusivity for the listed drug under section 360cc of this title.

(BB) Limitation

A drug that is granted tentative approval by the Secretary is not an approved drug and shall not have an effective approval until the Secretary issues an approval after any necessary additional review of the application.

(C) Civil action to obtain patent certainty

(i) Declaratory judgment absent infringement action

(I) In general

No action may be brought under section 2201 of title 28, by an applicant under paragraph (2) for a declaratory judgment with respect to a patent which is the subject of the certification referred to in subparagraph (B)(iii) unless—

(aa) the 45-day period referred to in such subparagraph has expired;

(bb) neither the owner of such patent nor the holder of the approved application under subsection (b) for the drug that is claimed by the patent or a use of which is claimed by the patent brought a civil action against the applicant for infringement of the

patent before the expiration of such period; and

(cc) in any case in which the notice provided under paragraph (2)(B) relates to noninfringement, the notice was accompanied by a document described in subclause (III).

(II) Filing of civil action

If the conditions described in items (aa), (bb), and as applicable, (cc) of subclause (I) have been met, the applicant referred to in such subclause may, in accordance with section 2201 of title 28, bring a civil action under such section against the owner or holder referred to in such subclause (but not against any owner or holder that has brought such a civil action against the applicant, unless that civil action was dismissed without prejudice) for a declaratory judgment that the patent is invalid or will not be infringed by the drug for which the applicant seeks approval, except that such civil action may be brought for a declaratory judgment that the patent will not be infringed only in a case in which the condition described in subclause (I)(cc) is applicable. A civil action referred to in this subclause shall be brought in the judicial district where the defendant has its principal place of business or a regular and established place of business.

(III) Offer of confidential access to application

For purposes of subclause (I)(cc), the document described in this subclause is a document providing an offer of confidential access to the application that is in the custody of the applicant under paragraph (2) for the purpose of determining whether an action referred to in subparagraph (B)(iii) should be brought. The document providing the offer of confidential access shall contain such restrictions as to persons entitled to access, and on the use and disposition of any information accessed, as would apply had a protective order been entered for the purpose of protecting trade secrets and other confidential business information. A request for access to an application under an offer of confidential access shall be considered acceptance of the offer of confidential access with the restrictions as to persons entitled to access, and on the use and disposition of any information accessed, contained in the offer of confidential access, and those restrictions and other terms of the offer of confidential access shall be considered terms of an enforceable contract. Any person provided an offer of confidential access shall review the application for the sole and limited purpose of evaluating possible infringement of the patent that is the subject of the certification under paragraph

(2)(A)(vii)(IV) and for no other purpose, and may not disclose information of no relevance to any issue of patent infringement to any person other than a person provided an offer of confidential access. Further, the application may be redacted by the applicant to remove any information of no relevance to any issue of patent infringement.

(ii) Counterclaim to infringement action

(I) In general

If an owner of the patent or the holder of the approved application under subsection (b) for the drug that is claimed by the patent or a use of which is claimed by the patent brings a patent infringement action against the applicant, the applicant may assert a counterclaim seeking an order requiring the holder to correct or delete the patent information submitted by the holder under subsection (b) or (c) on the ground that the patent does not claim either—

(aa) the drug for which the application was approved; or (bb) an approved method of using the drug.

(II) No independent cause of action

Subclause (I) does not authorize the assertion of a claim described in subclause (I) in any civil action or proceeding other than a counterclaim described in subclause (I).

(iii) No damages

An applicant shall not be entitled to damages in a civil action under clause (i) or a counterclaim under clause (ii).

(D) Forfeiture of 180-day exclusivity period

(i) Definition of forfeiture event

In this subparagraph, the term "forfeiture event", with respect to an application under this subsection, means the occurrence of any of the following:

(I) Failure to market

The first applicant fails to market the drug by the later of—

(aa) the earlier of the date that is—

(AA) 75 days after the date on which the approval of the application of the first applicant is made effective under subparagraph (B)(iii); or

(BB) 30 months after the date of submission of the application of the first applicant; or

(bb) with respect to the first applicant or any other applicant (which other applicant has received tentative approval), the date that is 75 days after the date as of which, as to each of the patents with respect to which the first applicant submitted and lawfully maintained a certification qualifying the first applicant for the

180-day exclusivity period under subparagraph (B)(iv), at least 1 of the following has occurred:

(AA) In an infringement action brought against that applicant with respect to the patent or in a declaratory judgment action brought by that applicant with respect to the patent, a court enters a final decision from which no appeal (other than a petition to the Supreme Court for a writ of certiorari) has been or can be taken that the patent is invalid or not infringed.

(BB) In an infringement action or a declaratory judgment action described in subitem (AA), a court signs a settlement order or consent decree that enters a final judgment that includes a finding that the patent is invalid or not infringed.

(CC) The patent information submitted under subsection (b) or (c) is withdrawn by the holder of the application approved under subsection (b).

(II) Withdrawal of application

The first applicant withdraws the application or the Secretary considers the application to have been withdrawn as a result of a determi-

nation by the Secretary that the application does not meet the requirements for approval under paragraph (4).

(III) Amendment of certification

The first applicant amends or withdraws the certification for all of the patents with respect to which that applicant submitted a certification qualifying the applicant for the 180-day exclusivity period.

(IV) Failure to obtain tentative approval

The first applicant fails to obtain tentative approval of the application within 30 months after the date on which the application is filed, unless the failure is caused by a change in or a review of the requirements for approval of the application imposed after the date on which the application is filed.

(V) Agreement with another applicant, the listed drug application holder, or a patent owner

The first applicant enters into an agreement with another applicant under this subsection for the drug, the holder of the application for the listed drug, or an owner of the patent that is the subject of the certification under paragraph

(2)(A)(vii)(IV), the Federal Trade Commission or the Attorney General files a complaint, and there is a final decision of the Federal Trade Commission or the court with regard to the complaint from which no appeal (other than a petition to the Supreme Court for a writ of certiorari) has been or can be taken that the agreement has violated the antitrust laws (as defined in section 12 of title 15, except that the term includes section 45 of title 15 to the extent that that section applies to unfair methods of competition).

(VI) Expiration of all patents

All of the patents as to which the applicant submitted a certification qualifying it for the 180-day exclusivity period have expired.

(ii) Forfeiture

The 180-day exclusivity period described in subparagraph (B)(iv) shall be forfeited by a first applicant if a forfeiture event occurs with respect to that first applicant.

(iii) Subsequent applicant

If all first applicants forfeit the 180-day exclusivity period under clause (ii)—

(I) approval of any application containing a certification described in

paragraph (2)(A)(vii)(IV) shall be made effective in accordance with subparagraph (B)(iii); and

(II) no applicant shall be eligible for a 180-day exclusivity period.

(E) If the Secretary decides to disapprove an application, the Secretary shall give the applicant notice of an opportunity for a hearing before the Secretary on the question of whether such application is approvable. If the applicant elects to accept the opportunity for hearing by written request within thirty days after such notice, such hearing shall commence not more than ninety days after the expiration of such thirty days unless the Secretary and the applicant otherwise agree. Any such hearing shall thereafter be conducted on an expedited basis and the Secretary's order thereon shall be issued within ninety days after the date fixed by the Secretary for filing final briefs.

(F) (i) If an application (other than an abbreviated new drug application) submitted under subsection (b) for a drug, no active ingredient (including any ester or salt of the active ingredient) of which has been approved in any other application under subsection (b), was approved during the period beginning January 1, 1982, and ending on September 24, 1984, the Secretary may not make the approval of an application submitted under this subsection which refers to the drug for which the subsection (b) application was submitted effective before the expiration of ten years from the date of the approval of the application under subsection (b).

(ii) If an application submitted under subsection (b) for a drug, no active ingredient (including any ester or salt of the active ingredient) of which has been approved in any other application under subsection (b), is approved after the date of the enactment of this subsection, no application may be submitted under this subsection which refers to the drug for which the subsection (b) application was submitted before the expiration of five years from the date of the approval of the application under subsection (b), except that such an application may be submitted under this subsection after the expiration of four years from the date of the approval of the subsection (b) application if it contains a certification of patent invalidity or noninfringement described in subclause (IV) of paragraph (2)(A)(vii). The approval of such an application shall be made effective in accordance with subparagraph (B) except that, if an action for patent infringement is commenced during the one-year period beginning forty-eight months after the date of the approval of the subsection (b) application, the thirty-month period referred to in subparagraph (B)(iii) shall be extended by such amount of time (if any) which is required for seven and one-half years to have elapsed from the date of approval of the subsection (b) application.

(iii) If an application submitted under subsection (b) for a drug, which includes an active ingredient (including any ester or salt of the active ingredient) that has been approved in another application approved under subsection (b), is approved after the date of enactment of

this subsection and if such application contains reports of new clinical investigations (other than bioavailability studies) essential to the approval of the application and conducted or sponsored by the applicant, the Secretary may not make the approval of an application submitted under this subsection for the conditions of approval of such drug in the subsection (b) application effective before the expiration of three years from the date of the approval of the application under subsection (b) for such drug.

(iv) If a supplement to an application approved under subsection (b) is approved after September 24, 1984 and the supplement contains reports of new clinical investigations (other than bioavailability studies) essential to the approval of the supplement and conducted or sponsored by the person submitting the supplement, the Secretary may not make the approval of an application submitted under this subsection for a change approved in the supplement effective before the expiration of three years from the date of the approval of the supplement under subsection (b).

(v) If an application (or supplement to an application) submitted under subsection (b) for a drug, which includes an active ingredient (including any ester or salt of the active ingredient) that has been approved in another application under subsection (b), was approved during the period beginning January 1, 1982, and ending on September 24, 1984, the Secretary may not make the approval of an application submitted under this subsection which

refers to the drug for which the subsection (b) application was submitted or which refers to a change approved in a supplement to the subsection (b) application effective before the expiration of two years from September 24, 1984.

(6) If a drug approved under this subsection refers in its approved application to a drug the approval of which was withdrawn or suspended for grounds described in the first sentence of subsection (e) or was withdrawn or suspended under this paragraph or which, as determined by the Secretary, has been withdrawn from sale for safety or effectiveness reasons, the approval of the drug under this subsection shall be withdrawn or suspended—

(A) for the same period as the withdrawal or suspension under subsection (e) of this paragraph, or

(B) if the listed drug has been withdrawn from sale, for the period of withdrawal from sale or, if earlier, the period ending on the date the Secretary determines that the withdrawal from sale is not for safety or effectiveness reasons.

(7) (A) (i) Within sixty days of September 24, 1984, the Secretary shall publish and make available to the public—

(I) a list in alphabetical order of the official and proprietary name of each drug which has been approved for safety and effectiveness under subsection (c) before September 24, 1984;

(II) the date of approval if the drug is approved after 1981 and the number of the application which was approved; and

(III) whether in vitro or in vivo bioequivalence studies, or both such studies, are required for applications filed under this subsection which will refer to the drug published.

(ii) Every thirty days after the publication of the first list under clause (i) the Secretary shall revise the list to include each drug which has been approved for safety and effectiveness under subsection (c) or approved under this subsection during the thirty-day period.

(iii) When patent information submitted under subsection (b) or (c) respecting a drug included on the list is to be published by the Secretary, the Secretary shall, in revisions made under clause (ii), include such information for such drug.

(B) A drug approved for safety and effectiveness under subsection (c) or approved under this subsection shall, for purposes of this subsection, be considered to have been published under subparagraph (A) on the date of its approval or September 24, 1984, whichever is later.

(C) If the approval of a drug was withdrawn or suspended for grounds described in the first sentence of subsection (e) or was withdrawn or suspended under paragraph (6) or if the Secretary determines that a drug has been withdrawn from sale for safety or effectiveness reasons, it may not be published in the list under subparagraph (A) or, if the withdrawal or suspension occurred after its publication in such list, it shall be immediately removed from such list—

(i) for the same period as the withdrawal or suspension under subsection (e) or paragraph (6), or

(ii) if the listed drug has been withdrawn from sale, for the period of withdrawal from sale or, if earlier, the period ending on the date the Secretary determines that the withdrawal from sale is not for safety or effectiveness reasons.

A notice of the removal shall be published in the Federal Register.

(8) For purposes of this subsection:

(A) (i) The term "bioavailability" means the rate and extent to which the active ingredient or therapeutic ingredient is absorbed from a drug and becomes available at the site of drug action.

(ii) For a drug that is not intended to be absorbed into the bloodstream, the Secretary may assess bioavailability by scientifically valid measurements intended to reflect the rate and extent to which the active ingredient or therapeutic ingredient becomes available at the site of drug action.

(B) A drug shall be considered to be bioequivalent to a listed drug if—

(i) the rate and extent of absorption of the drug do not show a significant difference from the rate and extent of absorption of the listed drug when administered at the same molar dose of the therapeutic ingredient under similar experimental conditions in either a single dose or multiple doses; or

(ii) the extent of absorption of the drug does not show a significant difference from the extent of absorption of the listed drug when administered at the same molar dose of the therapeutic ingredient under similar experimental conditions in either a single dose or multiple doses and the difference from the listed drug in the rate of absorption of the drug is intentional, is reflected in its proposed labeling, is not essential to the attainment of effective body drug concentrations on chronic use, and is considered medically insignificant for the drug.

(C) For a drug that is not intended to be absorbed into the bloodstream, the Secretary may establish alternative, scientifically valid methods to show bioequivalence if the alternative methods are expected to detect a significant difference between the drug and the listed drug in safety and therapeutic effect.

(9) The Secretary shall, with respect to each application submitted under this subsection, maintain a record of—

(A) the name of the applicant,

(B) the name of the drug covered by the application,

(C) the name of each person to whom the review of the chemistry of the application was assigned and the date of such assignment, and

(D) the name of each person to whom the bioequivalence review for such application was assigned and the date of such assignment.

The information the Secretary is required to maintain under this paragraph with respect to an application submitted under this subsection shall be made available to the public after the approval of such application.

(k) Records and reports; required information; regulations and orders; access to records

(1) In the case of any drug for which an approval of an application filed under subsection (b) or (j) is in effect, the applicant shall establish and maintain such records, and make such reports to the Secretary, of data relating to clinical experience and other data or information, received or otherwise obtained by such applicant with respect to such drug, as the Secretary may by general regulation, or by order with respect to such application, prescribe on the basis of a finding that such records and reports are necessary in order to enable the Secretary to determine, or facilitate a determination, whether there is or may be ground for invoking subsection (e) of this section. Regulations and orders issued under this subsection and under subsection (i) shall have due regard for the professional ethics of the medical profession and the interests of patients and shall provide, where the Secretary deems it to be appropriate, for the examination, upon request, by the persons to whom such regulations or orders are applicable, of similar information received or otherwise obtained by the Secretary.

(2) Every person required under this section to maintain records, and every person in charge or custody thereof, shall, upon request of an officer or employee designated by the Secretary, permit such officer or employee at all reasonable times to have access to and copy and verify such records.

(l) Public disclosure of safety and effectiveness data

Safety and effectiveness data and information which has been submitted in an application under subsection (b) for a drug and which has not previously been disclosed to the public shall be made available to the public, upon request, unless extraordinary circumstances are shown—

(1) if no work is being or will be undertaken to have the application approved,

(2) if the Secretary has determined that the application is not approvable and all legal appeals have been exhausted,

(3) if approval of the application under subsection (c) is withdrawn and all legal appeals have been exhausted,

(4) if the Secretary has determined that such drug is not a new drug, or

(5) upon the effective date of the approval of the first application under subsection (j) which refers to such drug or upon the date upon which the approval of an application under subsection (j) which refers to such drug could be made effective if such an application had been submitted.

(m) "Patent" defined

For purposes of this section, the term "patent" means a patent issued by the United States Patent and Trademark Office.

(n) Scientific advisory panels

(1) For the purpose of providing expert scientific advice and recommendations to the Secretary regarding a clinical investigation of a drug or the approval for marketing of a drug under section 262 of title 42, the Sec-

retary shall establish panels of experts or use panels of experts established before November 21, 1997, or both.

(2) The Secretary may delegate the appointment and oversight authority granted under section 394 of this title to a director of a center or successor entity within the Food and Drug Administration.

(3) The Secretary shall make appointments to each panel established under paragraph (1) so that each panel shall consist of—

(A) members who are qualified by training and experience to evaluate the safety and effectiveness of the drugs to be referred to the panel and who, to the extent feasible, possess skill and experience in the development, manufacture, or utilization of such drugs;

(B) members with diverse expertise in such fields as clinical and administrative medicine, pharmacy, pharmacology, pharmacoeconomics, biological and physical sciences, and other related professions;

(C) a representative of consumer interests, and a representative of interests of the drug manufacturing industry not directly affected by the matter to be brought before the panel; and

(D) two or more members who are specialists or have other expertise in the particular disease or condition for which the drug under review is proposed to be indicated.

Scientific, trade, and consumer organizations shall be afforded an opportunity to nominate individuals for appointment to the panels. No individual who is in the regular full-time employ of the United States and engaged in the administration of this Act [21 USCS

§§ 301 et seq.] may be a voting member of any panel. The Secretary shall designate one of the members of each panel to serve as chairman thereof.

(4) Each member of a panel shall publicly disclose all conflicts of interest that member may have with the work to be undertaken by the panel. No member of a panel may vote on any matter where the member or the immediate family of such member could gain financially from the advice given to the Secretary. The Secretary may grant a waiver of any conflict of interest requirement upon public disclosure of such conflict of interest if such waiver is necessary to afford the panel essential expertise, except that the Secretary may not grant a waiver for a member of a panel when the member's own scientific work is involved.

(5) The Secretary shall, as appropriate, provide education and training to each new panel member before such member participates in a panel's activities, including education regarding requirements under this chapter and related regulations of the Secretary, and the administrative processes and procedures related to panel meetings.

(6) Panel members (other than officers or employees of the United States), while attending meetings or conferences of a panel or otherwise engaged in its business, shall be entitled to receive compensation for each day so engaged, including traveltime, at rates to be fixed by the Secretary, but not to exceed the daily equivalent of the rate in effect for positions classified above grade GS-15 of the General Schedule. While serving away from their homes or regular places of business, panel members may be allowed travel expenses (including per diem in lieu of subsistence) as authorized by section 5703 of title 5, for

persons in the Government service employed intermittently.

(7) The Secretary shall ensure that scientific advisory panels meet regularly and at appropriate intervals so that any matter to be reviewed by such a panel can be presented to the panel not more than 60 days after the matter is ready for such review. Meetings of the panel may be held using electronic communication to convene the meetings.

(8) Within 90 days after a scientific advisory panel makes recommendations on any matter under its review, the Food and Drug Administration official responsible for the matter shall review the conclusions and recommendations of the panel, and notify the affected persons of the final decision on the matter, or of the reasons that no such decision has been reached. Each such final decision shall be documented including the rationale for the decision.

21 U.S.C. § 372. Examinations and investigations

(a) Authority to conduct

(1) The Secretary is authorized to conduct examinations and investigations for the purposes of this chapter through officers and employees of the Department or through any health, food, or drug officer or employee of any State, Territory, or political subdivision thereof, duly commissioned by the Secretary as an officer of the Department.

(2) (A) In addition to the authority established in paragraph (1), the Secretary, pursuant to a memorandum of understanding between the Secretary and the head of another Federal department or agency, is authorized to conduct examinations and investigations for the purposes of this chapter through the officers and employees of such other department or agency, subject to subparagraph (B). Such a memorandum shall include provisions to ensure adequate training of such officers and employees to conduct the examinations and investigations. The memorandum of understanding shall contain provisions regarding reimbursement. Such provisions may, at the sole discretion of the head of the other department or agency, require reimbursement, in whole or in part, from the Secretary for the examinations or investigations performed under this section by the officers or employees of the other department or agency.

(B) A memorandum of understanding under subparagraph (A) between the Secretary and another Federal department or agency is effective only in the case of examinations or inspections at facilities or other locations that are jointly regulated by the Secretary and such department or agency.

(C) For any fiscal year in which the Secretary and the head of another Federal department or agency carries out one or more examinations or inspections under a memorandum of understanding under subparagraph (A), the Secretary and the head of such department or agency shall with respect to their respective departments or agencies submit to the committees of jurisdiction (authorizing and appropriating) in the House of Representatives and the Senate a report that provides, for such year—

(i) the number of officers or employees that carried out one or more programs, projects, or activities under such memorandum;

(ii) the number of additional articles that were inspected or examined as a result of such memorandum; and

(iii) the number of additional examinations or investigations that were carried out pursuant to such memorandum.

(3) In the case of food packed in the Commonwealth of Puerto Rico or a Territory the Secretary shall attempt to make inspection of such food at the first point of entry within the United States when, in his opinion and with due regard to the enforcement of all the provisions of this chapter, the facilities at his disposal will permit of such inspection.

(4) For the purposes of this subsection, the term "United States" means the States and the District of Columbia.

(b) Availability to owner of part of analysis samples

Where a sample of a food, drug, or cosmetic is collected for analysis under this chapter the Secretary shall, upon request, provide a part of such official sample for exam-

ination or analysis by any person named on the label of the article, or the owner thereof, or his attorney or agent; except that the Secretary is authorized, by regulations, to make such reasonable exceptions from, and impose such reasonable terms and conditions relating to, the operation of this subsection as he finds necessary for the proper administration of the provisions of this chapter.

(c) Records of other departments and agencies

For purposes of enforcement of this chapter, records of any department or independent establishment in the executive branch of the Government shall be open to inspection by any official of the Department duly authorized by the Secretary to make such inspection.

(d) Information on patents for drugs

The Secretary is authorized and directed, upon request from the Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office, to furnish full and complete information with respect to such questions relating to drugs as the Director may submit concerning any patent application. The Secretary is further authorized, upon receipt of any such request, to conduct or cause to be conducted, such research as may be required.

(e) Powers of enforcement personnel

Any officer or employee of the Department designated by the Secretary to conduct examinations, investigations, or inspections under this chapter relating to counterfeit drugs may, when so authorized by the Secretary—

(1) carry firearms;

(2) execute and serve search warrants and arrest warrants;

(3) execute seizure by process issued pursuant to libel under section 334 of this title;

(4) make arrests without warrant for offenses under this chapter with respect to such drugs if the offense is committed in his presence or, in the case of a felony, if he has probable cause to believe that the person so arrested has committed, or is committing, such offense; and

(5) make, prior to the institution of libel proceedings under section 334(a)(2) of this title, seizures of drugs or containers or of equipment, punches, dies, plates, stones, labeling, or other things, if they are, or he has reasonable grounds to believe that they are, subject to seizure and condemnation under such section 334(a)(2). In the event of seizure pursuant to this paragraph (5), libel proceedings under section 334(a)(2) of this title shall be instituted promptly and the property seized be placed under the jurisdiction of the court.

21 U.S.C. § 393. Food and Drug Administration

. . .

(b) Mission

The Administration shall—

(1) promote the public health by promptly and efficiently reviewing clinical research and taking appropriate action on the marketing of regulated products in a timely manner;

(2) with respect to such products, protect the public health by ensuring that—

. . .

(B) human and veterinary drugs are safe and effective;

. . .

21 C.F.R. § 10.30. Citizen petition

(a) This section applies to any petition submitted by a person (including a person who is not a citizen of the United States) except to the extent that other sections of this chapter apply different requirements to a particular matter.

(b) A petition (including any attachments) must be submitted in accordance with § 10.20 and in the following form:

(Date) _____

Division of Dockets Management, Food and Drug Administration, Department of Health and Human Services, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

CITIZEN PETITION

The undersigned submits this petition under (relevant statutory sections, if known) of the (Federal Food, Drug, and Cosmetic Act or the Public Health Service Act or any other statutory provision for which authority has been delegated to the Commissioner of Food and Drugs under 21 CFR 5.10) to request the Commissioner of Food and Drugs to (issue, amend, or revoke a regulation or order or take or refrain from taking any other form of administrative action).

A. Action requested

((1) If the petition requests the Commissioner to issue, amend, or revoke a regulation, the exact wording of the existing regulation (if any) and the proposed regulation or amendment requested.)

((2) If the petition requests the Commissioner to issue, amend, or revoke an order, a copy of the exact wording

of the citation to the existing order (if any) and the exact wording requested for the proposed order.)

((3) If the petition requests the Commissioner to take or refrain from taking any other form of administrative action, the specific action or relief requested.)

B. Statement of grounds

(A full statement, in a well organized format, of the factual and legal grounds on which the petitioner relies, including all relevant information and views on which the petitioner relies, as well as representative information known to the petitioner which is unfavorable to the petitioner's position.)

C. Environmental impact

(A) claim for categorical exclusion under §§ 25.30, 25.31, 25.32, 25.33, or § 25.34 of this chapter or an environmental assessment under § 25.40 of this chapter.)

D. Economic impact

(The following information is to be submitted only when requested by the Commissioner following review of the petition: A statement of the effect of requested action on: (1) Cost (and price) increases to industry, government, and consumers; (2) productivity of wage earners, businesses, or government; (3) competition; (4) supplies of important materials, products, or services; (5) employment; and (6) energy supply or demand.)

E. Certification

The undersigned certifies, that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information

known to the petitioner which are unfavorable to the petition.

(Signature) _____

(Name of petitioner) _____

(Mailing address) _____

(Telephone number) _____

(c) A petition which appears to meet the requirements of paragraph (b) of this section and § 10.20 will be filed by the Division of Dockets Management, stamped with the date of filing, and assigned a docket number. The docket number identifies the file established by the Division of Dockets Management for all submissions relating to the petition, as provided in this part. Subsequent submissions relating to the matter must refer to the docket number and will be filed in the docket file. Related petitions may be filed together and given the same docket number. The Division of Dockets Management will promptly notify the petitioner in writing of the filing and docket number of a petition.

(d) An interested person may submit written comments to the Division of Dockets Management on a filed petition, which comments become part of the docket file. The comments are to specify the docket number of the petition and may support or oppose the petition in whole or in part. A request for alternative or different administrative action must be submitted as a separate petition.

(e) (1) The Commissioner shall, in accordance with paragraph (e)(2), rule upon each petition filed under paragraph (c) of this section, taking into consideration (i) available agency resources for the category of subject matter, (ii) the priority assigned to the petition considering both the category of subject matter involved and

the overall work of the agency, and (iii) time requirements established by statute.

(2) Except as provided in paragraph (e)(4) of this section, the Commissioner shall furnish a response to each petitioner within 180 days of receipt of the petition. The response will either:

(i) Approve the petition, in which case the Commissioner shall concurrently take appropriate action (e.g., publication of a FEDERAL REGISTER notice) implementing the approval;

(ii) Deny the petition; or

(iii) Provide a tentative response, indicating why the agency has been unable to reach a decision on the petition, e.g., because of the existence of other agency priorities, or a need for additional information. The tentative response may also indicate the likely ultimate agency response, and may specify when a final response may be furnished.

(3) The Commissioner may grant or deny such a petition, in whole or in part, and may grant such other relief or take other action as the petition warrants. The petitioner is to be notified in writing of the Commissioner's decision. The decision will be placed in the public docket file in the office of the Division of Dockets Management and may also be in the form of a notice published in the FEDERAL REGISTER.

(4) The Commissioner shall furnish a response to each petitioner within 90 days of receipt of a petition filed under section 505(j)(2)(C) of the act. The response will either approve or disapprove the petition. Agency action on a petition shall be governed by § 314.93 of this chapter.

(f) If a petition filed under paragraph (c) of this section requests the Commissioner to issue, amend, or revoke a regulation, § 10.40 or § 10.50 also apply.

(g) A petitioner may supplement, amend, or withdraw a petition in writing without agency approval and without prejudice to resubmission at anytime until the Commissioner rules on the petition, unless the petition has been referred for a hearing under parts 12, 13, 14, or 15. After a ruling or referral, a petition may be supplemented, amended, or withdrawn only with the approval of the Commissioner. The Commissioner may approve withdrawal, with or without prejudice against resubmission of the petition.

(h) In reviewing a petition the Commissioner may use the following procedures:

(1) Conferences, meetings, discussions, and correspondence under § 10.65.

(2) A hearing under parts 12, 13, 14, 15, or 16.

(3) A FEDERAL REGISTER notice requesting information and views.

(4) A proposal to issue, amend, or revoke a regulation, in accordance with § 10.40 or § 12.20.

(5) Any other specific public procedure established in this chapter and expressly applicable to the matter.

(i) The record of the administrative proceeding consists of the following:

(1) The petition, including all information on which it relies, filed by the Division of Dockets Management.

(2) All comments received on the petition, including all information submitted as a part of the comments.

(3) If the petition resulted in a proposal to issue, amend, or revoke a regulation, all of the documents specified in § 10.40(g).

(4) The record, consisting of any transcripts, minutes of meetings, reports, FEDERAL REGISTER notices, and other documents resulting from the optional procedures specified in paragraph (h) of this section, except a transcript of a closed portion of a public advisory committee meeting.

(5) The Commissioner's decision on the petition, including all information identified or filed by the Commissioner with the Division of Dockets Management as part of the record supporting the decision.

(6) All documents filed with the Division of Dockets Management under § 10.65(h).

(7) If a petition for reconsideration or for a stay of action is filed under paragraph (j) of this section, the administrative record specified in § 10.33(k) or § 10.35(h).

(j) The administrative record specified in paragraph (i) of this section is the exclusive record for the Commissioner's decision. The record of the administrative proceeding closes on the date of the Commissioner's decision unless some other date is specified. Thereafter any interested person may submit a petition for reconsideration under § 10.33 or a petition for stay of action under § 10.35. A person who wishes to rely upon information or views not included in the administrative record shall submit them to the Commissioner with a new petition to modify the decision in accordance with this section.

(k) This section does not apply to the referral of a matter to a United States attorney for the initiation of court enforcement action and related correspondence, or to requests, suggestions, and recommendations made informally in routine correspondence received by FDA. Routine correspondence does not constitute a petition within the meaning of this section unless it purports to meet the requirements of this section. Action on routine correspondence does not constitute final administrative action subject to judicial review under § 10.45.

(l) The Division of Dockets Management will maintain a chronological list of each petition filed under this section and § 10.85, but not of petitions submitted elsewhere in the agency under § 10.25(a)(1), showing:

(1) The docket number;

(2) The date the petition was filed by the Division of Dockets Management;

(3) The name of the petitioner;

(4) The subject matter involved; and

(5) The disposition of the petition.

21 C.F.R. § 314.50. Content and format of an application

Applications and supplements to approved applications are required to be submitted in the form and contain the information, as appropriate for the particular submission, required under this section. Three copies of the application are required: An archival copy, a review copy, and a field copy. An application for a new chemical entity will generally contain an application form, an index, a summary, five or six technical sections, case report tabulations of patient data, case report forms, drug samples, and labeling, including, if applicable, any Medication Guide required under part 208 of this chapter. Other applications will generally contain only some of those items, and information will be limited to that needed to support the particular submission. These include an application of the type described in section 505(b)(2) of the act, an amendment, and a supplement. The application is required to contain reports of all investigations of the drug product sponsored by the applicant, and all other information about the drug pertinent to an evaluation of the application that is received or otherwise obtained by the applicant from any source. FDA will maintain guidance documents on the format and content of applications to assist applicants in their preparation.

(a) Application form. The applicant shall submit a completed and signed application form that contains the following:

(1) The name and address of the applicant; the date of the application; the application number if previously issued (for example, if the application is a resubmission, an amendment, or a supplement); the name of the drug product, including its established, proprietary, code, and

chemical names; the dosage form and strength; the route of administration; the identification numbers of all investigational new drug applications that are referenced in the application; the identification numbers of all drug master files and other applications under this part that are referenced in the application; and the drug product's proposed indications for use.

(2) A statement whether the submission is an original submission, a 505(b)(2) application, a resubmission, or a supplement to an application under § 314.70.

(3) A statement whether the applicant proposes to market the drug product as a prescription or an over-the-counter product.

(4) A check-list identifying what enclosures required under this section the applicant is submitting.

(5) The applicant, or the applicant's attorney, agent, or other authorized official shall sign the application. If the person signing the application does not reside or have a place of business within the United States, the application is required to contain the name and address of, and be countersigned by, an attorney, agent, or other authorized official who resides or maintains a

(b) Index. The archival copy of the application is required to contain a comprehensive index by volume number and page number to the summary under paragraph (c) of this section, the technical sections under paragraph (d) of this section, and the supporting information under paragraph (f) of this section.

(c) Summary.

(1) An application is required to contain a summary of the application in enough detail that the reader may gain a good general understanding of the data and informa-

tion in the application, including an understanding of the quantitative aspects of the data. The summary is not required for supplements under § 314.70. Resubmissions of an application should contain an updated summary, as appropriate. The summary should discuss all aspects of the application, and synthesize the information into a well-structured and unified document. The summary should be written at approximately the level of detail required for publication in, and meet the editorial standards generally applied by, refereed scientific and medical journals. In addition to the agency personnel reviewing the summary in the context of their review of the application, FDA may furnish the summary to FDA advisory committee members and agency officials whose duties require an understanding of the application. To the extent possible, data in the summary should be presented in tabular and graphic forms. FDA has prepared a guideline under § 10.90(b) that provides information about how to prepare a summary. The summary required under this paragraph may be used by FDA or the applicant to prepare the Summary Basis of Approval document for public disclosure (under § 314.430(e)(2)(ii)) when the application is approved.

(2) The summary is required to contain the following information:

(i) The proposed text of the labeling, including, if applicable, any Medication Guide required under part 208 of this chapter, for the drug, with annotations to the information in the summary and technical sections of the application that support the inclusion of each statement in the labeling, and, if the application is for a prescription drug, statements describing the reasons for omitting a section or sub-

section of the labeling format in § 201.57 of this chapter.

(ii) A statement identifying the pharmacologic class of the drug and a discussion of the scientific rationale for the drug, its intended use, and the potential clinical benefits of the drug product.

(iii) A brief description of the marketing history, if any, of the drug outside the United States, including a list of the countries in which the drug has been marketed, a list of any countries in which the drug has been withdrawn from marketing for any reason related to safety or effectiveness, and a list of countries in which applications for marketing are pending. The description is required to describe both marketing by the applicant and, if known, the marketing history of other persons.

(iv) A summary of the chemistry, manufacturing, and controls section of the application.

(v) A summary of the nonclinical pharmacology and toxicology section of the application.

(vi) A summary of the human pharmacokinetics and bioavailability section of the application.

(vii) A summary of the microbiology section of the application (for anti-infective drugs only).

(viii) A summary of the clinical data section of the application, including the results of statistical analyses of the clinical trials.

(ix) A concluding discussion that presents the benefit and risk considerations related to the drug, including a discussion of any proposed additional studies or surveillance the applicant intends to conduct postmarketing.

(d) Technical sections.

The application is required to contain the technical sections described below. Each technical section is required to contain data and information in sufficient detail to permit the agency to make a knowledgeable judgment about whether to approve the application or whether grounds exist under section 505(d) of the act to refuse to approve the application. The required technical sections are as follows:

(1) Chemistry, manufacturing, and controls section. A section describing the composition, manufacture, and specification of the drug substance and the drug product, including the following:

(i) Drug substance. A full description of the drug substance including its physical and chemical characteristics and stability; the name and address of its manufacturer; the method of synthesis (or isolation) and purification of the drug substance; the process controls used during manufacture and packaging; and the specifications necessary to ensure the identity, strength, quality, and purity of the drug substance and the bioavailability of the drug products made from the substance, including, for example, tests, analytical procedures, and acceptance criteria relating to stability, sterility, particle size, and crystalline form. The application may provide additionally for the use of alternatives to meet any of these requirements, including alternative sources, process controls, and analytical procedures. Reference to the current edition of the U.S. Pharmacopeia and the National Formulary may satisfy relevant requirements in this paragraph.

(ii) (a) Drug product. A list of all components used in the manufacture of the drug product (regardless of whether they appear in the drug product) and a statement of the composition of the drug product; the specifications for each component; the name and address of each manufacturer of the drug product; a description of the manufacturing and packaging procedures and in-process controls for the drug product; the specifications necessary to ensure the identity, strength, quality, purity, potency, and bioavailability of the drug product, including, for example, tests, analytical procedures, and acceptance criteria relating to sterility, dissolution rate, container closure systems; and stability data with proposed expiration dating. The application may provide additionally for the use of alternatives to meet any of these requirements, including alternative components, manufacturing and packaging procedures, inprocess controls, and analytical procedures. Reference to the current edition of the U.S. Pharmacopeia and the National Formulary may satisfy relevant requirements in this paragraph.

(b) Unless provided by paragraph (d)(1)(ii)(a) of this section, for each batch of the drug product used to conduct a bioavailability or bioequivalence study described in § 320.38 or § 320.63 of this chapter or used to conduct a primary stability study: The batch production record; the specification for each component and for the drug product; the names and addresses of the sources of the active and noncompendial inactive components and of the container and closure system for the drug product; the name and address of each contract facility involved in the manufacture, processing, packaging, or testing of the drug product and identification of the operation

performed by each contract facility; and the results of any test performed on the components used in the manufacture of the drug product as required by § 211.84(d) of this chapter and on the drug product as required by § 211.165 of this chapter.

(c) The proposed or actual master production record, including a description of the equipment, to be used for the manufacture of a commercial lot of the drug product or a comparably detailed description of the production process for a representative batch of the drug product.

(iii) Environmental impact. The application is required to contain either a claim for categorical exclusion under § 25.30 or 25.31 of this chapter or an environmental assessment under § 25.40 of this chapter.

(iv) The applicant may, at its option, submit a complete chemistry, manufacturing, and controls section 90 to 120 days before the anticipated submission of the remainder of the application. FDA will review such early submissions as resources permit.

(v) The applicant shall include a statement certifying that the field copy of the application has been provided to the applicant's home FDA district office.

(2) Nonclinical pharmacology and toxicology section. A section describing, with the aid of graphs and tables, animal and in vitro studies with drug, including the following:

(i) Studies of the pharmacological actions of the drug in relation to its proposed therapeutic indica-

tion and studies that otherwise define the pharmacologic properties of the drug or are pertinent to possible adverse effects.

(ii) Studies of the toxicological effects of the drug as they relate to the drug's intended clinical uses, including, as appropriate, studies assessing the drug's acute, subacute, and chronic toxicity; carcinogenicity; and studies of toxicities related to the drug's particular mode of administration or conditions of use.

(iii) Studies, as appropriate, of the effects of the drug on reproduction and on the developing fetus.

(iv) Any studies of the absorption, distribution, metabolism, and excretion of the drug in animals.

(v) For each nonclinical laboratory study subject to the good laboratory practice regulations under Part 58 a statement that it was conducted in compliance with the good laboratory practice regulations in Part 58, or, if the study was not conducted in compliance with those regulations, a brief statement of the reason for the noncompliance.

(3) Human pharmacokinetics and bioavailability section. A section describing the human pharmacokinetic data and human bioavailability data, or information supporting a waiver of the submission of in vivo bioavailability data under Subpart B of Part 320, including the following:

(i) A description of each of the bioavailability and pharmacokinetic studies of the drug in humans performed by or on behalf of the applicant that includes a description of the analytical procedures and statistical methods used in each study and a

statement with respect to each study that it either was conducted in compliance with the institutional review board regulations in Part 56, or was not subject to the regulations under § 56.104 or § 56.105, and that it was conducted in compliance with the informed consent regulations in Part 50.

(ii) If the application describes in the chemistry, manufacturing, and controls section tests, analytical procedures, and acceptance criteria needed to assure the bioavailability of the drug product or drug substance, or both, a statement in this section of the rationale for establishing the tests, analytical procedures, and acceptance criteria, including data and information supporting the rationale.

(iii) A summarizing discussion and analysis of the pharmacokinetics and metabolism of the active ingredients and the bioavailability or bioequivalence, or both, of the drug product.

(4) Microbiology section. If the drug is an anti-infective drug, a section describing the microbiology data, including the following:

(i) A description of the biochemical basis of the drug's action on microbial physiology.

(ii) A description of the antimicrobial spectra of the drug, including results of in vitro preclinical studies to demonstrate concentrations of the drug required for effective use.

(iii) A description of any known mechanisms of resistance to the drug, including results of any known epidemiologic studies to demonstrate prevalence of resistance factors.

(iv) A description of clinical microbiology laboratory procedures (for example, in vitro sensitivity discs) needed for effective use of the drug.

(5) Clinical data section. A section describing the clinical investigations of the drug, including the following:

(i) A description and analysis of each clinical pharmacology study of the drug, including a brief comparison of the results of the human studies with the animal pharmacology and toxicology data.

(ii) A description and analysis of each controlled clinical study pertinent to a proposed use of the drug, including the protocol and a description of the statistical analyses used to evaluate the study. If the study report is an interim analysis, this is to be noted and a projected completion date provided. Controlled clinical studies that have not been analyzed in detail for any reason (e.g., because they have been discontinued or are incomplete) are to be included in this section, including a copy of the protocol and a brief description of the results and status of the study.

(iii) A description of each uncontrolled clinical study, a summary of the results, and a brief statement explaining why the study is classified as uncontrolled.

(iv) A description and analysis of any other data or information relevant to an evaluation of the safety and effectiveness of the drug product obtained or otherwise received by the applicant from any source, foreign or domestic, including information derived from clinical investigations, including controlled and uncontrolled studies of

uses of the drug other than those proposed in the application, commercial marketing experience, reports in the scientific literature, and unpublished scientific papers.

(v) An integrated summary of the data demonstrating substantial evidence of effectiveness for the claimed indications. Evidence is also required to support the dosage and administration section of the labeling, including support for the dosage and dose interval recommended. The effectiveness data shall be presented by gender, age, and racial subgroups and shall identify any modifications of dose or dose interval needed for specific subgroups. Effectiveness data from other subgroups of the population of patients treated, when appropriate, such as patients with renal failure or patients with different levels of severity of the disease, also shall be presented.

(vi) A summary and updates of safety information, as follows:

(a) The applicant shall submit an integrated summary of all available information about the safety of the drug product, including pertinent animal data, demonstrated or potential adverse effects of the drug, clinically significant drug/drug interactions, and other safety considerations, such as data from epidemiological studies of related drugs. The safety data shall be presented by gender, age, and racial subgroups. When appropriate, safety data from other subgroups of the population of patients treated also shall be presented, such as for patients with renal failure or patients with different levels of severity of the disease. A description of any statistical analyses per-

formed in analyzing safety data should also be included, unless already included under paragraph (d)(5)(ii) of this section.

(b) The applicant shall, under section 505(i) of the act, update periodically its pending application with new safety information learned about the drug that may reasonably affect the statement of contraindications, warnings, precautions, and adverse reactions in the draft labeling and, if applicable, any Medication Guide required under part 208 of this chapter. These "safety update reports" are required to include the same kinds of information (from clinical studies, animal studies, and other sources) and are required to be submitted in the same format as the integrated summary in paragraph (d)(5)(vi)(a) of this section. In addition, the reports are required to include the case report forms for each patient who died during a clinical study or who did not complete the study because of an adverse event (unless this requirement is waived). The applicant shall submit these reports (1) 4 months after the initial submission; (2) following receipt of an approvable letter; and (3) at other times as requested by FDA. Prior to the submission of the first such report, applicants are encouraged to consult with FDA regarding further details on its form and content.

(vii) If the drug has a potential for abuse, a description and analysis of studies or information related to abuse of the drug, including a proposal for scheduling under the Controlled Substances Act. A description of any studies related to overdosage is

also required, including information on dialysis, antidotes, or other treatments, if known.

(viii) An integrated summary of the benefits and risks of the drug, including a discussion of why the benefits exceed the risks under the conditions stated in the labeling.

(ix) A statement with respect to each clinical study involving human subjects that it either was conducted in compliance with the institutional review board regulations in part 56, or was not subject to the regulations under § 56.104 or § 56.105, and that it was conducted in compliance with the informed consent regulations in part 50.

(x) If a sponsor has transferred any obligations for the conduct of any clinical study to a contract research organization, a statement containing the name and address of the contract research organization, identification of the clinical study, and a listing of the obligations transferred. If all obligations governing the conduct of the study have been transferred, a general statement of this transfer—in lieu of a listing of the specific obligations transferred—may be submitted.

(xi) If original subject records were audited or reviewed by the sponsor in the course of monitoring any clinical study to verify the accuracy of the case reports submitted to the sponsor, a list identifying each clinical study so audited or reviewed.

(6) Statistical section. A section describing the statistical evaluation of clinical data, including the following:

(i) A copy of the information submitted under paragraph (d)(5)(ii) of this section concerning the description and analysis of each controlled clinical study, and the documentation and supporting statistical analyses used in evaluating the controlled clinical studies.

(ii) A copy of the information submitted under paragraph (d)(5)(vi)(a) of this section concerning a summary of information about the safety of the drug product, and the documentation and supporting statistical analyses used in evaluating the safety information.

(7) Pediatric use section. A section describing the investigation of the drug for use in pediatric populations, including an integrated summary of the information (the clinical pharmacology studies, controlled clinical studies, or uncontrolled clinical studies, or other data or information) that is relevant to the safety and effectiveness and benefits and risks of the drug in pediatric populations for the claimed indications, a reference to the full descriptions of such studies provided under paragraphs (d)(3) and (d)(5) of this section, and information required to be submitted under § 314.55.

(e) Samples and labeling.

(1) Upon request from FDA, the applicant shall submit the samples described below to the places identified in the agency's request. FDA will generally ask applicants to submit samples directly to two or more agency laboratories that will perform all necessary tests on the samples and validate the applicant's analytical procedures.

(i) Four representative samples of the following, each sample in sufficient quantity to permit FDA to

perform three times each test described in the application to determine whether the drug substance and the drug product meet the specifications given in the application:

(a) The drug product proposed for marketing;

(b) The drug substance used in the drug product from which the samples of the drug product were taken; and

(c) Reference standards and blanks (except that reference standards recognized in an official compendium need not be submitted).

(ii) Samples of the finished market package, if requested by FDA.

(2) The applicant shall submit the following in the archival copy of the application:

(i) Three copies of the analytical procedures and related descriptive information contained in the chemistry, manufacturing, and controls section under paragraph (d)(1) of this section for the drug substance and the drug product that are necessary for FDA's laboratories to perform all necessary tests on the samples and to validate the applicant's analytical procedures. The related descriptive information includes a description of each sample; the proposed regulatory specifications for the drug; a detailed description of the procedures of analysis; supporting data for accuracy, specificity, precision and ruggedness; and complete results of the applicant's tests on each sample.

(ii) Copies of the label and all labeling for the drug product (including, if applicable, any Medication Guide required under part 208 of this chap-

ter) for the drug product (4 copies of draft labeling or 12 copies of final printed labeling).

(f) Case report forms and tabulations. The archival copy of the application is required to contain the following case report tabulations and case report forms:

(1) Case report tabulations. The application is required to contain tabulations of the data from each adequate and well-controlled study under § 314.126 (Phase 2 and Phase 3 studies as described in §§ 312.21 (b) and (c) of this chapter), tabulations of the data from the earliest clinical pharmacology studies (Phase 1 studies as described in § 312.21(a) of this chapter), and tabulations of the safety data from other clinical studies. Routine submission of other patient data from uncontrolled studies is not required. The tabulations are required to include the data on each patient in each study, except that the applicant may delete those tabulations which the agency agrees, in advance, are not pertinent to a review of the drug's safety or effectiveness. Upon request, FDA will discuss with the applicant in a "pre-NDA" conference those tabulations that may be appropriate for such deletion. Barring unforeseen circumstances, tabulations agreed to be deleted at such a conference will not be requested during the conduct of FDA's review of the application. If such unforeseen circumstances do occur, any request for deleted tabulations will be made by the director of the FDA division responsible for reviewing the application, in accordance with paragraph (f)(3) of this section.

(2) Case report forms. The application is required to contain copies of individual case report forms for each patient who died during a clinical study or who did not complete the study because of an adverse event, whether believed to be drug related or not, including patients

receiving reference drugs or placebo. This requirement may be waived by FDA for specific studies if the case report forms are unnecessary for a proper review of the study.

(3) Additional data. The applicant shall submit to FDA additional case report forms and tabulations needed to conduct a proper review of the application, as requested by the director of the FDA division responsible for reviewing the application. The applicant's failure to submit information requested by FDA within 30 days after receipt of the request may result in the agency viewing any eventual submission as a major amendment under § 314.60 and extending the review period as necessary. If desired by the applicant, the FDA division director will verify in writing any request for additional data that was made orally.

(4) Applicants are invited to meet with FDA before submitting an application to discuss the presentation and format of supporting information. If the applicant and FDA agree, the applicant may submit tabulations of patient data and case report forms in a form other than hard copy, for example, on microfiche or computer tapes.

(g) Other. The following general requirements apply to the submission of information within the summary under paragraph (c) of this section and within the technical sections under paragraph (d) of this section.

(1) The applicant ordinarily is not required to resubmit information previously submitted, but may incorporate the information by reference. A reference to information submitted previously is required to identify the file by name, reference number, volume, and page number in the agency's records where the information

can be found. A reference to information submitted to the agency by a person other than the applicant is required to contain a written statement that authorizes the reference and that is signed by the person who submitted the information.

(2) The applicant shall submit an accurate and complete English translation of each part of the application that is not in English. The applicant shall submit a copy of each original literature publication for which an English translation is submitted.

(3) If an applicant who submits a new drug application under section 505(b) of the act obtains a "right of reference or use," as defined under § 314.3(b), to an investigation described in clause (A) of section 505(b)(1) of the act, the applicant shall include in its application a written statement signed by the owner of the data from each such investigation that the applicant may rely on in support of the approval of its application, and provide FDA access to, the underlying raw data that provide the basis for the report of the investigation submitted in its application.

(h) Patent information. The application is required to contain the patent information described under § 314.53.

(i) Patent certification—

(1) Contents. A 505(b)(2) application is required to contain the following:

(i) Patents claiming drug, drug product, or method of use.

(A) Except as provided in paragraph (i)(2) of this section, a certification with respect to each patent issued by the United States Patent and Trademark Office that, in the opinion of the

applicant and to the best of its knowledge, claims a drug (the drug product or drug substance that is a component of the drug product) on which investigations that are relied upon by the applicant for approval of its application were conducted or that claims an approved use for such drug and for which information is required to be filed under section 505(b) and (c) of the act and § 314.53. For each such patent, the applicant shall provide the patent number and certify, in its opinion and to the best of its knowledge, one of the following circumstances:

(1) That the patent information has not been submitted to FDA. The applicant shall entitle such a certification "Paragraph I Certification";

(2) That the patent has expired. The applicant shall entitle such a certification "Paragraph II Certification";

(3) The date on which the patent will expire. The applicant shall entitle such a certification "Paragraph III Certification"; or

(4) That the patent is invalid, unenforceable, or will not be infringed by the manufacture, use, or sale of the drug product for which the application is submitted. The applicant shall entitle such a certification "Paragraph IV Certification". This certification shall be submitted in the following form:

I, (name of applicant), certify that Patent No. (is invalid, unenforceable, or will not be infringed by the manufacture, use, or sale of) (name of proposed drug product) for which this application is submitted.

The certification shall be accompanied by a statement that the applicant will comply with the requirements under § 314.52(a) with respect to providing a notice to each owner of the patent or their representatives and to the holder of the approved application for the drug product which is claimed by the patent or a use of which is claimed by the patent and with the requirements under § 314.52(c) with respect to the content of the notice.

(B) If the drug on which investigations that are relied upon by the applicant were conducted is itself a licensed generic drug of a patented drug first approved under section 505(b) of the act, the appropriate patent certification under this section with respect to each patent that claims the first-approved patented drug or that claims an approved use for such a drug.

(ii) No relevant patents. If, in the opinion of the applicant and to the best of its knowledge, there are no patents described in paragraph (i)(1)(i) of this section, a certification in the following form:

In the opinion and to the best knowledge of (name of applicant), there are no patents that claim the drug or drugs on which investigations that are relied upon in this application were conducted or that claim a use of such drug or drugs.

(iii) Method of use patent.

(A) If information that is submitted under section 505(b) or (c) of the act and § 314.53 is for a method of use patent, and the labeling for the drug product for which the applicant is seeking approval does not include any indications that are covered by the use patent, a statement explaining that the method of use patent does not claim any of the proposed indications.

(B) If the labeling of the drug product for which the applicant is seeking approval includes an indication that, according to the patent information submitted under section 505(b) or (c) of the act and § 314.53 or in the opinion of the applicant, is claimed by a use patent, the applicant shall submit an applicable certification under paragraph (i)(1)(i) of this section.

(2) Method of manufacturing patent. An applicant is not required to make a certification with respect to any patent that claims only a method of manufacturing the drug product for which the applicant is seeking approval.

(3) Licensing agreements. If a 505(b)(2) application is for a drug or method of using a drug claimed by a patent and the applicant has a licensing agreement with the patent owner, the applicant shall submit a certification under paragraph (i)(1)(i)(A)(4) of this section ("Paragraph IV Certification") as to that patent and a statement that it has been granted a patent license. If the patent owner consents to an immediate effective date upon approval of the 505(b)(2) application, the application shall contain a written statement from the patent owner that it has a licensing agreement with the applicant and that it consents to an immediate effective date.

(4) Late submission of patent information. If a patent described in paragraph (i)(1)(i)(A) of this section is issued and the holder of the approved application for the patented drug does not submit the required information on the patent within 30 days of issuance of the patent, an applicant who submitted a 505(b)(2) application that, before the submission of the patent information, contained an appropriate patent certification is not required to submit an amended certification. An applicant whose 505(b)(2) application is filed after a late submission of patent information or whose 505(b)(2) application was previously filed but did not contain an appropriate patent certification at the time of the patent submission shall submit a certification under paragraph (i)(1)(i) or (i)(1)(ii) of this section or a statement under paragraph (i)(1)(iii) of this section as to that patent.

(5) Disputed patent information. If an applicant disputes the accuracy or relevance of patent information submitted to FDA, the applicant may seek a confirmation of the correctness of the patent information in accordance with the procedures under § 314.53(f). Unless the patent information is withdrawn or changed, the applicant must submit an appropriate certification for each relevant patent.

(6) Amended certifications. A certification submitted under paragraphs (i)(1)(i) through (i)(1)(iii) of this section may be amended at any time before the effective date of the approval of the application. An applicant shall submit an amended certification as an amendment to a pending application or by letter to an approved application. If an applicant with a pending application voluntarily makes a patent certification for an untimely filed patent, the applicant may withdraw the patent certification for the untimely filed patent. Once an amend-

ment or letter for the change in certification has been submitted, the application will no longer be considered to be one containing the prior certification.

(i) After finding of infringement. An applicant who has submitted a certification under paragraph (i)(1)(i)(A)(4) of this section and is sued for patent infringement within 45 days of the receipt of notice sent under § 314.52 shall amend the certification if a final judgment in the action is entered finding the patent to be infringed unless the final judgment also finds the patent to be invalid. In the amended certification, the applicant shall certify under paragraph (i)(1)(i)(A)(3) of this section that the patent will expire on a specific date.

(ii) After removal of a patent from the list. If a patent is removed from the list, any applicant with a pending application (including a tentatively approved application with a delayed effective date) who has made a certification with respect to such patent shall amend its certification. The applicant shall certify under paragraph (i)(1)(ii) of this section that no patents described in paragraph (i)(1)(i) of this section claim the drug or, if other relevant patents claim the drug, shall amend the certification to refer only to those relevant patents. In the amendment, the applicant shall state the reason for the change in certification (that the patent is or has been removed from the list). A patent that is the subject of a lawsuit under § 314.107(c) shall not be removed from the list until FDA determines either that no delay in effective dates of approval is required under that section as a result of the lawsuit, that the patent has expired, or that any such period of delay in effective dates of approval is ended. An

applicant shall submit an amended certification as an amendment to a pending application. Once an amendment for the change has been submitted, the application will no longer be considered to be one containing a certification under paragraph (i)(1)(i)(A)(4) of this section.

(iii) Other amendments.

(A) Except as provided in paragraphs (i)(4) and (i)(6)(iii)(B) of this section, an applicant shall amend a submitted certification if, at any time before the effective date of the approval of the application, the applicant learns that the submitted certification is no longer accurate.

(B) An applicant is not required to amend a submitted certification when information on an otherwise applicable patent is submitted after the effective date of approval for the 505(b)(2) application.

(j) Claimed exclusivity. A new drug product, upon approval, may be entitled to a period of marketing exclusivity under the provisions of § 314.108. If an applicant believes its drug product is entitled to a period of exclusivity, it shall submit with the new drug application prior to approval the following information:

(1) A statement that the applicant is claiming exclusivity.

(2) A reference to the appropriate paragraph under § 314.108 that supports its claim.

(3) If the applicant claims exclusivity under § 314.108(b)(2), information to show that, to the best of its knowledge or belief, a drug has not previously been approved under section 505(b) of the act containing any

active moiety in the drug for which the applicant is seeking approval.

(4) If the applicant claims exclusivity under § 314.108(b)(4) or (b)(5), the following information to show that the application contains "new clinical investigations" that are "essential to approval of the application or supplement" and were "conducted or sponsored by the applicant:"

(i) "New clinical investigations." A certification that to the best of the applicant's knowledge each of the clinical investigations included in the application meets the definition of "new clinical investigation" set forth in § 314.108(a).

(ii) "Essential to approval." A list of all published studies or publicly available reports of clinical investigations known to the applicant through a literature search that are relevant to the conditions for which the applicant is seeking approval, a certification that the applicant has thoroughly searched the scientific literature and, to the best of the applicant's knowledge, the list is complete and accurate and, in the applicant's opinion, such published studies or publicly available reports do not provide a sufficient basis for the approval of the conditions for which the applicant is seeking approval without reference to the new clinical investigation(s) in the application, and an explanation as to why the studies or reports are insufficient.

(iii) "Conducted or sponsored by." If the applicant was the sponsor named in the Form FDA-1571 for an investigational new drug application (IND) under which the new clinical investigation(s) that is essential to the approval of its application was conducted,

identification of the IND by number. If the applicant was not the sponsor of the IND under which the clinical investigation(s) was conducted, a certification that the applicant or its predecessor in interest provided substantial support for the clinical investigation(s) that is essential to the approval of its application, and information supporting the certification. To demonstrate "substantial support," an applicant must either provide a certified statement from a certified public accountant that the applicant provided 50 percent or more of the cost of conducting the study or provide an explanation of why FDA should consider the applicant to have conducted or sponsored the study if the applicant's financial contribution to the study is less than 50 percent or the applicant did not sponsor the investigational new drug. A predecessor in interest is an entity, e.g., a corporation, that the applicant has taken over, merged with, or purchased, or from which the applicant has purchased all rights to the drug. Purchase of nonexclusive rights to a clinical investigation after it is completed is not sufficient to satisfy this definition.

(k) Financial certification or disclosure statement. The application shall contain a financial certification or disclosure statement or both as required by part 54 of this chapter.

(l) Format of an original application. (1) Archival copy. The applicant must submit a complete archival copy of the application that contains the information required under paragraphs (a) through (f) of this section. FDA will maintain the archival copy during the review of the application to permit individual reviewers to refer to information that is not contained in their particular

technical sections of the application, to give other agency personnel access to the application for official business, and to maintain in one place a complete copy of the application. Except as required by paragraph (l)(1)(i) of this section, applicants may submit the archival copy on paper or in electronic format provided that electronic submissions are made in accordance with part 11 of this chapter.

(i) Labeling. The content of labeling required under § 201.100(d)(3) of this chapter (commonly referred to as the package insert or professional labeling), including all text, tables, and figures, must be submitted to the agency in electronic format as described in paragraph (l)(5) of this section. This requirement is in addition to the requirements of paragraph (e)(2)(ii) of this section that copies of the formatted label and all labeling be submitted. Submissions under this paragraph must be made in accordance with part 11 of this chapter, except for the requirements of § 11.10(a), (c) through (h), and (k), and the corresponding requirements of § 11.30.

(ii) [Reserved]

(2) Review copy. The applicant must submit a review copy of the application. Each of the technical sections, described in paragraphs (d)(1) through (d)(6) of this section, in the review copy is required to be separately bound with a copy of the application form required under paragraph (a) of this section and a copy of the summary required under paragraph (c) of this section.

(3) Field copy. The applicant must submit a field copy of the application that contains the technical section described in paragraph (d)(1) of this section, a copy of the application form required under paragraph (a) of this

section, a copy of the summary required under paragraph (c) of this section, and a certification that the field copy is a true copy of the technical section described in paragraph (d)(1) of this section contained in the archival and review copies of the application.

(4) Binding folders. The applicant may obtain from FDA sufficient folders to bind the archival, the review, and the field copies of the application.

(5) Electronic format submissions. Electronic format submissions must be in a form that FDA can process, review, and archive. FDA will periodically issue guidance on how to provide the electronic submission (e.g., method of transmission, media, file formats, preparation and organization of files).

21 C.F.R. § 314.80. Postmarketing reporting of adverse drug experiences

(a) Definitions. The following definitions of terms apply to this section:

Adverse drug experience. Any adverse event associated with the use of a drug in humans, whether or not considered drug related, including the following: An adverse event occurring in the course of the use of a drug product in professional practice; an adverse event occurring from drug overdose whether accidental or intentional; an adverse event occurring from drug abuse; an adverse event occurring from drug withdrawal; and any failure of expected pharmacological action.

Disability. A substantial disruption of a person's ability to conduct normal life functions.

Life-threatening adverse drug experience. Any adverse drug experience that places the patient, in the view of the initial reporter, at immediate risk of death from the adverse drug experience as it occurred, i.e., it does not include an adverse drug experience that, had it occurred in a more severe form, might have caused death.

Serious adverse drug experience. Any adverse drug experience occurring at any dose that results in any of the following outcomes: Death, a life-threatening adverse drug experience, inpatient hospitalization or prolongation of existing hospitalization, a persistent or significant disability/ incapacity, or a congenital anomaly/birth defect. Important medical events that may not result in death, be life-threatening, or require hospitalization may be considered a serious adverse drug experience when, based upon appropriate medical judgment, they may jeopardize the patient or subject and may require medical or surgical intervention to prevent one

of the outcomes listed in this definition. Examples of such medical events include allergic bronchospasm requiring intensive treatment in an emergency room or at home, blood dyscrasias or convulsions that do not result in inpatient hospitalization, or the development of drug dependency or drug abuse.

Unexpected adverse drug experience. Any adverse drug experience that is not listed in the current labeling for the drug product. This includes events that may be symptomatically and pathophysiologically related to an event listed in the labeling, but differ from the event because of greater severity or specificity. For example, under this definition, hepatic necrosis would be unexpected (by virtue of greater severity) if the labeling only referred to elevated hepatic enzymes or hepatitis. Similarly, cerebral thromboembolism and cerebral vasculitis would be unexpected (by virtue of greater specificity) if the labeling only listed cerebral vascular accidents. "Unexpected," as used in this definition, refers to an adverse drug experience that has not been previously observed (i.e., included in the labeling) rather than from the perspective of such experience not being anticipated from the pharmacological properties of the pharmaceutical product.

(b) Review of adverse drug experiences. Each applicant having an approved application under § 314.50 or, in the case of a 505(b)(2) application, an effective approved application, shall promptly review all adverse drug experience information obtained or otherwise received by the applicant from any source, foreign or domestic, including information derived from commercial marketing experience, postmarketing clinical investigations, postmarketing epidemiological/surveillance studies, reports in the scientific literature, and unpublished scientific

papers. Applicants are not required to resubmit to FDA adverse drug experience reports forwarded to the applicant by FDA; however, applicants must submit all followup information on such reports to FDA. Any person subject to the reporting requirements under paragraph (c) of this section shall also develop written procedures for the surveillance, receipt, evaluation, and reporting of postmarketing adverse drug experiences to FDA.

(c) Reporting requirements. The applicant shall report to FDA adverse drug experience information, as described in this section. The applicant shall submit two copies of each report described in this section to the Central Document Room, 5901-B Ammendale Rd., Beltsville, MD 20705-1266. FDA may waive the requirement for the second copy in appropriate instances.

(1) (i) Postmarketing 15-day "Alert reports". The applicant shall report each adverse drug experience that is both serious and unexpected, whether foreign or domestic, as soon as possible but in no case later than 15 calendar days of initial receipt of the information by the applicant.

(ii) Postmarketing 15-day "Alert reports"—followup. The applicant shall promptly investigate all adverse drug experiences that are the subject of these postmarketing 15-day Alert reports and shall submit followup reports within 15 calendar days of receipt of new information or as requested by FDA. If additional information is not obtainable, records should be maintained of the unsuccessful steps taken to seek additional information. Postmarketing 15-day Alert reports and followups to them shall be submitted under separate cover.

(iii) Submission of reports. The requirements of paragraphs (c)(1)(i) and (c)(1)(ii) of this section, concerning the submission of postmarketing 15-day Alert reports, shall also apply to any person other than the applicant (nonapplicant) whose name appears on the label of an approved drug product as a manufacturer, packer, or distributor. To avoid unnecessary duplication in the submission to FDA of reports required by paragraphs (c)(1)(i) and (c)(1)(ii) of this section, obligations of a nonapplicant may be met by submission of all reports of serious adverse drug experiences to the applicant. If a nonapplicant elects to submit adverse drug experience reports to the applicant rather than to FDA, the nonapplicant shall submit each report to the applicant within 5 calendar days of receipt of the report by the nonapplicant, and the applicant shall then comply with the requirements of this section. Under this circumstance, the nonapplicant shall maintain a record of this action which shall include:

(A) A copy of each adverse drug experience report;

(B) The date the report was received by the nonapplicant;

(C) The date the report was submitted to the applicant; and

(D) The name and address of the applicant.

(iv) Report identification. Each report submitted under this paragraph shall bear prominent identification as to its contents, i.e., "15-day Alert report," or "15-day Alert report-followup."

(2) Periodic adverse drug experience reports.

(i) The applicant shall report each adverse drug experience not reported under paragraph (c)(1)(i) of this section at quarterly intervals, for 3 years from the date of approval of the application, and then at annual intervals. The applicant shall submit each quarterly report within 30 days of the close of the quarter (the first quarter beginning on the date of approval of the application) and each annual report within 60 days of the anniversary date of approval of the application. Upon written notice, FDA may extend or reestablish the requirement that an applicant submit quarterly reports, or require that the applicant submit reports under this section at different times than those stated. For example, the agency may reestablish a quarterly reporting requirement following the approval of a major supplement. Followup information to adverse drug experiences submitted in a periodic report may be submitted in the next periodic report.

(ii) Each periodic report is required to contain: (a) a narrative summary and analysis of the information in the report and an analysis of the 15-day Alert reports submitted during the reporting interval (all 15-day Alert reports being appropriately referenced by the applicant's patient identification number, adverse reaction term(s), and date of submission to FDA); (b) a FDA Form 3500A (Adverse Reaction Report) for each adverse drug experience not reported under paragraph (c)(1)(i) of this section (with an index consisting of a line listing of the applicant's patient identification number and adverse reaction term(s)); and (c) a history of actions taken since the last report because of adverse drug experiences (for example, labeling changes or studies initiated).

(iii) Periodic reporting, except for information regarding 15-day Alert reports, does not apply to adverse drug experience information obtained from postmarketing studies (whether or not conducted under an investigational new drug application), from reports in the scientific literature, and from foreign marketing experience.

(d) Scientific literature.

(1) A 15-day Alert report based on information from the scientific literature is required to be accompanied by a copy of the published article. The 15-day reporting requirements in paragraph (c)(1)(i) of this section (i.e., serious, unexpected adverse drug experiences) apply only to reports found in scientific and medical journals either as case reports or as the result of a formal clinical trial.

(2) As with all reports submitted under paragraph (c)(1)(i) of this section, reports based on the scientific literature shall be submitted on FDA Form 3500A or comparable format as prescribed by paragraph (f) of this section. In cases where the applicant believes that preparing the FDA Form 3500A constitutes an undue hardship, the applicant may arrange with the Division of Pharmacovigilance and Epidemiology for an acceptable alternative reporting format.

(e) Postmarketing studies.

(1) An applicant is not required to submit a 15-day Alert report under paragraph (c) of this section for an adverse drug experience obtained from a postmarketing study (whether or not conducted under an investigational new drug application) unless the applicant concludes that there is a reasonable possibility that the drug caused the adverse experience.

(2) The applicant shall separate and clearly mark reports of adverse drug experiences that occur during a postmarketing study as being distinct from those experiences that are being reported spontaneously to the applicant.

(f) Reporting FDA Form 3500.

(1) Except as provided in paragraph (f)(3) of this section, the applicant shall complete FDA Form 3500A for each report of an adverse drug experience (foreign events may be submitted either on an FDA Form 3500A or, if preferred, on a CIOMS I form).

(2) Each completed FDA Form 3500A should refer only to an individual patient or a single attached publication.

(3) Instead of using FDA Form 3500A an applicant may use a computer-generated FDA Form 3500A or other alternative format (e.g., a computer-generated tape or tabular listing) provided that: (i) The content of the alternative format is equivalent in all elements of information to those specified in FDA Form 3500A; and (ii) the format is agreed to in advance by MedWatch: The FDA Medical Products Reporting Program.

(4) Ten copies or fewer of FDA Form 3500A and/or a copy of the instructions for completing the form may be obtained from the Division of Pharmacovigilance and Epidemiology (HFD-730), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. More than 10 copies of the form may be obtained by writing to the Consolidated Forms and Publications Distribution Center, Washington Commerce Center, 3222 Hubbard Rd., Landover, MD 20785.

(g) Multiple reports. An applicant should not include in reports under this section any adverse drug experiences that occurred in clinical trials if they were previously submitted as part of the approved application. If a report applies to a drug for which an applicant holds more than one approved application, the applicant should submit the report to the application that was first approved. If a report refers to more than one drug marketed by an applicant, the applicant should submit the report to the application for the drug listed first in the report.

(h) Patient privacy. An applicant should not include in reports under this section the names and addresses of individual patients; instead, the applicant should assign a unique code number to each report, preferably not more than eight characters in length. The applicant should include the name of the reporter from whom the information was received. Names of patients, health care professionals, hospitals, and geographical identifiers in adverse drug experience reports are not releasable to the public under FDA's public information regulations in Part 20.

(i) Recordkeeping. The applicant shall maintain for a period of 10 years records of all adverse drug experiences known to the applicant, including raw data and any correspondence relating to adverse drug experiences.

(j) Withdrawal of approval. If an applicant fails to establish and maintain records and make reports required under this section, FDA may withdraw approval of the application and, thus, prohibit continued marketing of the drug product that is the subject of the application.

(k) Disclaimer. A report or information submitted by an applicant under this section (and any release by FDA of that report or information) does not necessarily reflect a

conclusion by the applicant or FDA that the report or information constitutes an admission that the drug caused or contributed to an adverse effect. An applicant need not admit, and may deny, that the report or information submitted under this section constitutes an admission that the drug caused or contributed to an adverse effect. For purposes of this provision, the term "applicant" also includes any person reporting under paragraph (c)(1)(iii) of this section.

21 C.F.R. § 314.81. Other postmarketing reports

(a) Applicability. Each applicant shall make the reports for each of its approved applications and abbreviated applications required under this section and section 505(k) of the act.

(b) Reporting requirements. The applicant shall submit to the Food and Drug Administration at the specified times two copies of the following reports:

(1) NDA—Field alert report. The applicant shall submit information of the following kinds about distributed drug products and articles to the FDA district office that is responsible for the facility involved within 3 working days of receipt by the applicant. The information may be provided by telephone or other rapid communication means, with prompt written followup. The report and its mailing cover should be plainly marked: "NDA—Field Alert Report."

(i) Information concerning any incident that causes the drug product or its labeling to be mistaken for, or applied to, another article.

(ii) Information concerning any bacteriological contn, or any significant chemical, physical, or other change or deterioration in the distributed drug product, or any failure of one or more distributed batches of the drug product to meet the specification established for it in the application.

(2) Annual report. The applicant shall submit each year within 60 days of the anniversary date of U.S. approval of the application, two copies of the report to the FDA division responsible for reviewing the application. Each annual report is required to be accompanied by a completed transmittal Form FDA 2252 (Transmittal

of Periodic Reports for Drugs for Human Use), and must include all the information required under this section that the applicant received or otherwise obtained during the annual reporting interval that ends on the U.S. anniversary date. The report is required to contain in the order listed:

(i) Summary. A brief summary of significant new information from the previous year that might affect the safety, effectiveness, or labeling of the drug product. The report is also required to contain a brief description of actions the applicant has taken or intends to take as a result of this new information, for example, submit a labeling supplement, add a warning to the labeling, or initiate a new study. The summary shall briefly state whether labeling supplements for pediatric use have been submitted and whether new studies in the pediatric population to support appropriate labeling for the pediatric population have been initiated. Where possible, an estimate of patient exposure to the drug product, with special reference to the pediatric population (neonates, infants, children, and adolescents) shall be provided, including dosage form.

(ii) Distribution data. Information about the quantity of the drug product distributed under the approved application, including that distributed to distributors. The information is required to include the National Drug Code (NDC) number, the total number of dosage units of each strength or potency distributed (e.g., 100,000/5 milligram tablets, 50,000/10 milliliter vials), and the quantities distributed for domestic use and the quantities distributed for foreign use. Disclosure of financial or pricing data is not required.

(iii) Labeling.

(a) Currently used professional labeling, patient brochures or package inserts (if any), and a representative sample of the package labels.

(b) The content of labeling required under § 201.100(d)(3) of this chapter (i.e., the package insert or professional labeling), including all text, tables, and figures, must be submitted in electronic format. Electronic format submissions must be in a form that FDA can process, review, and archive. FDA will periodically issue guidance on how to provide the electronic submission (e.g., method of transmission, media, file formats, preparation and organization of files). Submissions under this paragraph must be made in accordance with part 11 of this chapter, except for the requirements of § 11.10(a), (c) through (h), and (k), and the corresponding requirements of § 11.30.

(c) A summary of any changes in labeling that have been made since the last report listed by date in the order in which they were implemented, or if no changes, a statement of that fact.

(iv) Chemistry, manufacturing, and controls changes.

(a) Reports of experiences, investigations, studies, or tests involving chemical or physical properties, or any other properties of the drug (such as the drug's behavior or properties in relation to microorganisms, including both the

effects of the drug on microorganisms and the effects of microorganisms on the drug). These reports are only required for new information that may affect FDA's previous conclusions about the safety or effectiveness of the drug product.

(b) A full description of the manufacturing and controls changes not requiring a supplemental application under § 314.70 (b) and (c), listed by date in the order in which they were implemented.

(v) Nonclinical laboratory studies. Copies of unpublished reports and summaries of published reports of new toxicological findings in animal studies and in vitro studies (e.g., mutagenicity) conducted by, or otherwise obtained by, the applicant concerning the ingredients in the drug product. The applicant shall submit a copy of a published report if requested by FDA.

(vi) Clinical data.

(a) Published clinical trials of the drug (or abstracts of them), including clinical trials on safety and effectiveness; clinical trials on new uses; biopharmaceutic, pharmacokinetic, and clinical pharmacology studies; and reports of clinical experience pertinent to safety (for example, epidemiologic studies or analyses of experience in a monitored series of patients) conducted by or otherwise obtained by the applicant. Review articles, papers describing the use of the drug product in medical practice, papers and abstracts in which the drug is used as a research tool, promotional articles, press

clippings, and papers that do not contain tabulations or summaries of original data should not be reported.

(b) Summaries of completed unpublished clinical trials, or prepublication manuscripts if available, conducted by, or otherwise obtained by, the applicant. Supporting information should not be reported. (A study is considered completed 1 year after it is concluded.)

(c) Analysis of available safety and efficacy data in the pediatric population and changes proposed in the labeling based on this information. An assessment of data needed to ensure appropriate labeling for the pediatric population shall be included.

(vii) Status reports of postmarketing study commitments. A status report of each postmarketing study of the drug product concerning clinical safety, clinical efficacy, clinical pharmacology, and nonclinical toxicology that is required by FDA (e.g., accelerated approval clinical benefit studies, pediatric studies) or that the applicant has committed, in writing, to conduct either at the time of approval of an application for the drug product or a supplement to an application, or after approval of the application or a supplement. For pediatric studies, the status report shall include a statement indicating whether postmarketing clinical studies in pediatric populations were required by FDA under § 201.23 of this chapter. The status of these postmarketing studies shall be reported annually until FDA notifies the applicant, in writing, that the agency concurs with the applicant's determination that the study commitment has been fulfilled or that the study is

either no longer feasible or would no longer provide useful information.

(a) Content of status report. The following information must be provided for each postmarketing study reported under this paragraph:

(1) Applicant's name.

(2) Product name. Include the approved drug product's established name and proprietary name, if any.

(3) NDA, ANDA, and supplement number.

(4) Date of U.S. approval of NDA or ANDA.

(5) Date of postmarketing study commitment.

(6) Description of postmarketing study commitment. The description must include sufficient information to uniquely describe the study. This information may include the purpose of the study, the type of study, the patient population addressed by the study and the indication(s) and dosage(s) that are to be studied.

(7) Schedule for completion and reporting of the postmarketing study commitment. The schedule should include the actual or projected dates for submission of the study protocol to FDA, completion of patient accrual or initiation of an animal study, completion of the study, submission of the final study report to FDA, and any additional milestones or submissions for

which projected dates were specified as part of the commitment. In addition, it should include a revised schedule, as appropriate. If the schedule has been previously revised, provide both the original schedule and the most recent, previously submitted revision.

(8) Current status of the postmarketing study commitment. The status of each postmarketing study should be categorized using one of the following terms that describes the study's status on the anniversary date of U.S. approval of the application or other agreed upon date:

(i) Pending. The study has not been initiated, but does not meet the criterion for delayed.

(ii) Ongoing. The study is proceeding according to or ahead of the original schedule described under paragraph (b)(2)(vii)(a)(7) of this section.

(iii) Delayed. The study is behind the original schedule described under paragraph (b)(2)(vii)(a)(7) of this section.

(iv) Terminated. The study was ended before completion but a final study report has not been submitted to FDA.

(v) Submitted. The study has been completed or terminated and a final

study report has been submitted to FDA.

(9) Explanation of the study's status. Provide a brief description of the status of the study, including the patient accrual rate (expressed by providing the number of patients or subjects enrolled to date, and the total planned enrollment), and an explanation of the study's status identified under paragraph (b)(2)(vii)(a)(8) of this section. If the study has been completed, include the date the study was completed and the date the final study report was submitted to FDA, as applicable. Provide a revised schedule, as well as the reason(s) for the revision, if the schedule under paragraph (b)(2)(vii)(a)(7) of this section has changed since the last report.

(b) Public disclosure of information. Except for the information described in this paragraph, FDA may publicly disclose any information described in paragraph (b)(2)(vii) of this section, concerning a postmarketing study, if the agency determines that the information is necessary to identify the applicant or to establish the status of the study, including the reasons, if any, for failure to conduct, complete, and report the study. Under this section, FDA will not publicly disclose trade secrets, as defined in § 20.61 of this chapter, or information, described in § 20.63 of this chapter, the disclosure of which would constitute an unwarranted invasion of personal privacy.

(viii) Status of other postmarketing studies. A status report of any postmarketing study not included under paragraph (b)(2)(vii) of this section that is being performed by, or on behalf of, the applicant. A status report is to be included for any chemistry, manufacturing, and controls studies that the applicant has agreed to perform and for all product stability studies.

(ix) Log of outstanding regulatory business. To facilitate communications between FDA and the applicant, the report may, at the applicant's discretion, also contain a list of any open regulatory business with FDA concerning the drug product subject to the application (e.g., a list of the applicant's unanswered correspondence with the agency, a list of the agency's unanswered correspondence with the applicant).

(3) Other reporting—

(i) Advertisements and promotional labeling. The applicant shall submit specimens of mailing pieces and any other labeling or advertising devised for promotion of the drug product at the time of initial dissemination of the labeling and at the time of initial publication of the advertisement for a prescription drug product. Mailing pieces and labeling that are designed to contain samples of a drug product are required to be complete, except the sample of the drug product may be omitted. Each submission is required to be accompanied by a completed transmittal Form FDA-2253 (Transmittal of Advertisements and Promotional Labeling for Drugs for Human Use) and is required to include a copy of the product's current professional labeling. Form FDA-2253 may be obtained from the PHS Forms and

Publications Distribution Center, 12100 Parklawn Dr., Rockville, MD 20857.

(ii) Special reports. Upon written request the agency may require that the applicant submit the reports under this section at different times than those stated.

(iii) Withdrawal of approved drug product from sale.

(a) The applicant shall submit on Form FDA 2657 (Drug Product Listing), within 15 working days of the withdrawal from sale of a drug product, the following information:

(1) The National Drug Code (NDC) number.

(2) The identity of the drug product by established name and by proprietary name.

(3) The new drug application or abbreviated application number.

(4) The date of withdrawal from sale. It is requested but not required that the reason for withdrawal of the drug product from sale be included with the information.

(b) The applicant shall submit each Form FDA-2657 to the Records Repository Team (HFD-143), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857.

(c) Reporting under paragraph (b)(3)(iii) of this section constitutes compliance with the requirements under § 207.30(a) of this chapter

to report "at the discretion of the registrant when the change occurs."

(c) General requirements—

(1) Multiple applications. For all reports required by this section, the applicant shall submit the information common to more than one application only to the application first approved, and shall not report separately on each application. The submission is required to identify all the applications to which the report applies.

(2) Patient identification. Applicants should not include in reports under this section the names and addresses of individual patients; instead, the applicant should code the patient names whenever possible and retain the code in the applicant's files. The applicant shall maintain sufficient patient identification information to permit FDA, by using that information alone or along with records maintained by the investigator of a study, to identify the name and address of individual patients; this will ordinarily occur only when the agency needs to investigate the reports further or when there is reason to believe that the reports do not represent actual results obtained.

(d) Withdrawal of approval. If an applicant fails to make reports required under this section, FDA may withdraw approval of the application and, thus, prohibit continued marketing of the drug product that is the subject of the application.

21 C.F.R. § 314.105. Approval of an application and an abbreviated application

. . .

(c) FDA will approve an application after it determines that the drug meets the statutory standards for safety and effectiveness, manufacturing and controls, and labeling, and an abbreviated application after it determines that the drug meets the statutory standards for manufacturing and controls, labeling, and, where applicable, bioequivalence. While the statutory standards apply to all drugs, the many kinds of drugs that are subject to the statutory standards and the wide range of uses for those drugs demand flexibility in applying the standards. Thus FDA is required to exercise its scientific judgment to determine the kind and quantity of data and information an applicant is required to provide for a particular drug to meet the statutory standards. FDA makes its views on drug products and classes of drugs available through guidance documents, recommendations, and other statements of policy.

21 C.F.R. § 314.150 Withdrawal of approval of an application or abbreviated application

(a) The Food and Drug Administration will notify the applicant, and, if appropriate, all other persons who manufacture or distribute identical, related, or similar drug products as defined in §§ 310.6 and 314.151(a) of this chapter and for a new drug afford an opportunity for a hearing on a proposal to withdraw approval of the application or abbreviated new drug application under section 505(e) of the act and under the procedure in § 314.200, if any of the following apply:

(1) The Secretary of Health and Human Services has suspended the approval of the application or abbreviated application for a new drug on a finding that there is an imminent hazard to the public health. FDA will promptly afford the applicant an expedited hearing following summary suspension on a finding of imminent hazard to health.

(2) FDA finds:

(i) That clinical or other experience, tests, or other scientific data show that the drug is unsafe for use under the conditions of use upon the basis of which the application or abbreviated application was approved; or

(ii) That new evidence of clinical experience, not contained in the application or not available to FDA until after the application or abbreviated application was approved, or tests by new methods, or tests by methods not deemed reasonably applicable when the application or abbreviated application was approved, evaluated together with the evidence available when

the application or abbreviated application was approved, reveal that the drug is not shown to be safe for use under the conditions of use upon the basis of which the application or abbreviated application was approved; or

(iii) Upon the basis of new information before FDA with respect to the drug, evaluated together with the evidence available when the application or abbreviated application was approved, that there is a lack of substantial evidence from adequate and well-controlled investigations as defined in § 314.126, that the drug will have the effect it is purported or represented to have under the conditions of use prescribed, recommended, or suggested in its labeling; or

(iv) That the application or abbreviated application contains any untrue statement of a material fact; or

(v) That the patent information prescribed by section 505(c) of the act was not submitted within 30 days after the receipt of written notice from FDA specifying the failure to submit such information; or

(b) FDA may notify the applicant, and, if appropriate, all other persons who manufacture or distribute identical, related, or similar drug products as defined in § 310.6, and for a new drug afford an opportunity for a hearing on a proposal to withdraw approval of the application or abbreviated new drug application under section 505(e) of the act and under the procedure in § 314.200, if the agency finds:

(1) That the applicant has failed to establish a system for maintaining required records, or has repeatedly or deliberately failed to maintain required records or to make required reports under section 505(k) or 507(g) of the act and § 314.80, § 314.81, or § 314.98, or that the applicant has refused to permit access to, or copying or verification of, its records.

(2) That on the basis of new information before FDA, evaluated together with the evidence available when the application or abbreviated application was approved, the methods used in, or the facilities and controls used for, the manufacture, processing, and packing of the drug are inadequate to ensure and preserve its identity, strength, quality, and purity and were not made adequate within a reasonable time after receipt of written notice from the agency.

(3) That on the basis of new information before FDA, evaluated together with the evidence available when the application or abbreviated application was approved, the labeling of the drug, based on a fair evaluation of all material facts, is false or misleading in any particular, and the labeling was not corrected by the applicant within a reasonable time after receipt of written notice from the agency.

(4) That the applicant has failed to comply with the notice requirements of section 510(j)(2) of the act.

(5) That the applicant has failed to submit bioavailability or bioequivalence data required under part 320 of this chapter.

(6) The application or abbreviated application does not contain an explanation of the omission of a report of any investigation of the drug product sponsored by the applicant, or an explanation of the omission of other

information about the drug pertinent to an evaluation of the application or abbreviated application that is received or otherwise obtained by the applicant from any source.

(7) That any nonclinical laboratory study that is described in the application or abbreviated application and that is essential to show that the drug is safe for use under the conditions prescribed, recommended, or suggested in its labeling was not conducted in compliance with the good laboratory practice regulations in part 58 of this chapter and no reason for the noncompliance was provided or, if it was, the differences between the practices used in conducting the study and the good laboratory practice regulations do not support the validity of the study.

(8) Any clinical investigation involving human subjects described in the application or abbreviated application, subject to the institutional review board regulations in part 56 of this chapter or informed consent regulations in part 50 of this chapter, was not conducted in compliance with those regulations such that the rights or safety of human subjects were not adequately protected.

(9) That the applicant or contract research organization that conducted a bioavailability or bioequivalence study described in § 320.38 or § 320.63 of this chapter that is contained in the application or abbreviated application refuses to permit an inspection of facilities or records relevant to the study by a properly authorized officer or employee of the Department of Health and Human Services or refuses to submit reserve samples of the drug products used in the study when requested by FDA.

(10) That the labeling for the drug product that is the subject of the abbreviated new drug application is no longer consistent with that for the listed drug referred to in the abbreviated new drug application, except for differences approved in the abbreviated new drug application or those differences resulting from:

(i) A patent on the listed drug issued after approval of the abbreviated new drug application; or

(ii) Exclusivity accorded to the listed drug after approval of the abbreviated new drug application that do not render the drug product less safe or effective than the listed drug for any remaining, nonprotected condition(s) of use.

(c) FDA will withdraw approval of an application or abbreviated application if the applicant requests its withdrawal because the drug subject to the application or abbreviated application is no longer being marketed, provided none of the conditions listed in paragraphs (a) and (b) of this section applies to the drug. FDA will consider a written request for a withdrawal under this paragraph to be a waiver of an opportunity for hearing otherwise provided for in this section. Withdrawal of approval of an application or abbreviated application under this paragraph is without prejudice to refiling.

(d) FDA may notify an applicant that it believes a potential problem associated with a drug is sufficiently serious that the drug should be removed from the market and may ask the applicant to waive the opportunity for hearing otherwise provided for under this section, to permit FDA to withdraw approval of the application or abbreviated application for the product, and to remove voluntarily the product from the market. If the applicant agrees, the agency will not make a finding under para-

graph (b) of this section, but will withdraw approval of the application or abbreviated application in a notice published in the Federal Register that contains a brief summary of the agency's and the applicant's views of the reasons for withdrawal.

UNITED STATES DISTRICT COURT
E.D. TEXAS
SHERMAN DIVISION

No. 4:05CV84
Dec. 7, 2006

ROZLYN ACKERMANN, Individually and as a Personal Representative of Martin Lindsey Ackermann,

—v.—

WYETH PHARMACEUTICALS.

Arnold Anderson (Andy) Vickery, Vickery & Waldner, Houston, TX, for Rozlyn Ackermann, Individually and as a Personal Representative of Martin Lindsey Ackermann.

David Booth Alden, Edward J. Sebold, Mark Hermann, Jones Day, Cleveland, OH, David S. Rutkowski, Jones Day, Washington, DC, Susan E. Burnett, Michael R. Klatt, Clark Thomas & Winters, Austin, TX, for Wyeth Pharmaceuticals.

MEMORANDUM ADOPTING REPORT AND RECOMMENDATION OF THE UNITED STATES MAGISTRATE JUDGE

MICHAEL H. SCHNEIDER, District Judge.

Came on for consideration the above-referenced civil action, this Court having heretofore ordered this case be referred to Magistrate Judge Don D. Bush for all pretrial purposes.

The report of the United States Magistrate Judge, which contains proposed findings of fact and recommendations for the disposition of Defendant's Motion for Summary Judgment (Docket No. 77), has been presented for consideration. The Court having made a *de novo* review of the objections raised by Plaintiff thereto, is of the opinion that the findings and conclusions of the Magistrate Judge are correct, and the objections of the Plaintiff are without merit. Therefore, the Court hereby adopts the findings and conclusions of the Magistrate Judge as the findings and conclusions of this Court. It is, therefore,

ORDERED that the Magistrate Judge's Report is **ADOPTED** as the opinion of the Court. It is further

ORDERED that Defendant's Motion for Summary Judgment is hereby the **GRANTED.**

DON D. BUSH, Magistrate Judge.

REPORT AND RECOMMENDATION OF UNITED STATES MAGISTRATE JUDGE

Before the Court is Defendant's Motion for Summary Judgement. (Docket No. 77). The facts of the case are essentially not in dispute. On January 17, 2002, Plano

police were dispatched to the home of Martin Ackermann ("Ackermann"). Ackermann's son had called 911 notifying the dispatcher that his father had shot himself. Police encountered the son and his mother, the Plaintiff in this action, outside the house "screaming and crying." The son told police that "he (Ackermann) shot himself and there's blood everywhere." The police entered the residence and found Ackermann in an office /study area. According to reports and the autopsy results, he had shot himself in the mouth with a revolver.

Ackermann had been depressed. Mrs. Ackermann told hospital personnel a number of factors which may have played some role in his depression. She stated that she had recently been treated for breast cancer, that Ackermann's brother had died of cancer and that his mother had Alzheimer's disease. There was also information that his business had suffered since the 9-11 attacks and that he had been seeing a psychiatrist. His wife said he had been taking Selexis [sic] and she thought the medication had caused him to talk strangely. (Def.'s Mot. Summ. J., Ex. L). A toxicology exam revealed only the presence of citalopram which is marketed under the brand name of Celexa, manufactured by Forest Laboratories. (*Id.*, Ex. K). Medical reports on admission to ER also note that he was taking Celexa. (*Id.*, Ex. M).

Ackermann was treated for depression prior to the time he saw Dr. Sonn. There is no dispute that he was taking Celexa prior to the time he saw Dr. Sonn. He filled a prescription for Celexa on November 12, 2001. Celexa is a selective serotonin reuptake inhibitor ("SSRI"). He was referred to Dr. Sonn by a lawyer friend. He saw Dr. Sonn on the evening of January 4th and again on January 5th, 2002. Dr. Sonn testified that he also saw Ackermann on January 9th and January 12th, 2002. Dr. Sonn testified that he gave Ackermann a

sample pack of Effexor. Effexor is manufactured by Wyeth Pharmaceuticals ("Wyeth"). The pack contained dosage for two weeks. The sample pack Dr. Sonn gave Ackermann was labeled "Sample-Not For Sale" on both the box and the pill-blister pack inside the box. For the first week, Ackermann was to take one pill of 37.5 milligram strength. The second week, the dosage increased to 75 milligram strength. According to Mrs. Ackermann, her husband took three 37.5 milligram tablets on January 6th, 7th and 8th respectively, and then four more 75 milligram tablets on the 9th through the 12th. It does not appear he took any Effexor after January 12th. Dr. Sonn testified that he last saw Ackermann on the 12th and that Ackermann complained that the medication was affecting his "manhood." Ackermann terminated his relationship with Dr. Sonn on January 12th. It appears from Mrs. Ackermann's deposition that Ackermann resumed taking Celexa after discontinuing Effexor. She claims that Dr. Sonn put him back on Celexa. In any event, the presence of Celexa in his blood indicates that he went back on Celexa and there does not appear to be much dispute on this issue.

When Dr. Sonn treated Ackermann, he (a) reviewed the Effexor package insert that was reproduced in the Physicians' Desk Reference (Def.'s Mot. Summ. J., Ex. C, Sonn. Dep. at 42:11-43:25, Dec. 19, 2005); (b) was aware that depressed patients have a heightened risk of suicide (*Id.* at 18:16-19, 28:4-12, 28:15-19); (c) was aware of the need to monitor depressed patients for suicidal thinking and monitored Ackermann for that purpose (*Id.* at 32:10-14, 34:3-5); (d) was aware of claims that Effexor might be causally related to suicide or suicidality and considered those risks in treating Ackermann (*Id.* at 38:9-18); (e) chose (and still chooses) not to discuss suicide-related risks with patients directly

because mentioning suicide might prompt suicidal thinking or cause patients to stop treatment (*Id.* at 1117:20-22, 119:20- 120:20, 121:21-25); (f) was aware that some Effexor patients attempt suicide, have suicidal ideation, and experience agitation or akathisia, but saw no signs of those in Ackermann (*Id.* at 41:2-8, 44:1-7, 44:12, 45:7-15, 48:6-9, 98:23-25, 133:12-14, 136:14-18; 150:18-22); (g) was aware that patients who have taken large doses of Effexor for substantial periods of time may need to be tapered off Effexor (*Id.* at 25:20-25, 147:1-3); and (h) saw no need to taper Ackermann off Effexor because he had taken only a low dose for a short period of time (*Id.* at 145:17-146:2, 148:4-10).

Despite his current knowledge of Ackermann's suicide and changes to antidepressant warnings made since January 2002, Dr. Sonn (a) still believes Effexor's January 2002 package insert gave adequate warnings about the drug's suicide-related risks (*Id.* at 53:22-54:?, 116:5-8); (b) would prescribe Effexor to Ackermann today (*Id.* at 157:10-13); (c) would take the same approach to warnings that he did with the Ackermanns in January 2002 (*Id.* at 127:16-19; 130:5-8; 157:2-7; 187:11-19; 188:7-20); and (d) believes Effexor's benefits outweigh its risks (*Id.* at 20:23-21:2).

Standard

Summary judgment is proper "if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." Fed.R.Civ.P. 56(c). Disputes about material facts are genuine "if the evidence is such that a reasonable jury could return a verdict for the nonmoving party."

Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248 (1986). The evidence and inferences from the summary judgment record must be viewed in the light most favorable to the nonmovant. *Minter v. Great Am. Ins. Co.*, 423 F.3d 460, 465 (5th Cir.2005); *See also McNeil v. Wyeth*, 462 F.3d 364 (5th Cir.2006).

Fraud and Misrepresentation

In her complaint, Plaintiff sued for fraud and misrepresentation. In her amended response, Plaintiff has abandoned these theories of recovery. Therefore, Defendant is entitled to judgement on these claims.

Breach of Warranties and DTPA

In her complaint, Plaintiff also sues for breach of express and implied warranties. She never specifies what implied warranties nor what express warranty she is referring to in her complaint. Her response to Defendant's Motion for Summary Judgement on this ground is no model of clarity. The gist of Plaintiff's complaint is that not enough was disclosed, not that there was a disclosure that somehow was breached. She claims that implied warranties were breached without much specification. Plaintiff "bootstraps" her breach of warranty claim into a Deceptive Trade Practices Act ("DTPA") claim under Tex. Bus. Comm.Code section 17.50(a). Wyeth argues that there can be no breach of warranty in that Ackermann never purchased Effexor from Wyeth nor did he do so from Dr. Sonn. In fact, Wyeth argues that Dr. Sonn merely gave Ackermann free samples. Plaintiff argues that he can be a consumer under the DTPA since he "purchased or acquired" medical services from Dr. Sonn. Privity is not required to enforce an

express warranty under the DTPA. *U.S. Tire-Tech, Inc. v. Boeran, B.V.*, 110 S.W.3d 194 (Tex.App.-Houston [1st Dist.] 2003, *pet. denied*). Privity is not required in order to be a consumer under the DTPA. *Amstadt v. U.S. Brass Corp.*, 919 S.W.2d 644, 649 (Tex.1996); *Cameron v. Terrell & Garrett, Inc.*, 618 S.W.2d 535, 540-41 (Tex.1981). Yet, the DTPA does not define or create any warranties. *Parkway Co. v. Woodruff*, 901 S.W.2d 434, 438 (Tex.1995). Warranties actionable under the DTPA, both express and implied, must be first recognized by common law or created by statute. *Id.*

Sections 2.313, 2.314 and 2.315 of the Tex. Bus. Comm.Code contemplate a sale: ". . . any affirmation of fact or promise made by the seller to the buyer," § 2.313(a)(1); ". . . a warranty that the goods shall be merchantable is implied in a contract for their sale," § 2.314; and "where the seller at the time of contracting has reason to know any particular purpose for which the goods are required . . ." § 2.315. A sale consists in the passing of title from the seller to the buyer for a price. *Id.* at § 2.106. A buyer means a person who buys or contracts to buy goods. *Id.* at § 2.103(a)(1). A seller means a person who sells or contracts to sell goods. The definition of goods by implication excludes services. *Id.* at § 2.105. A contract refers to a *sale* of goods. Bottom line, under strict statutory interpretation, there must be an underlying sale to trigger the applicability of the Uniform Commercial Code ("UCC").

In any event, the Court agrees with the Defendant that no express warranty was identified, but more importantly, there has been no showing that Ackermann relied on any express warranty. In Texas, reliance is not only relevant to, but an element of proof, for sustaining a claim for breach of an express warranty. *See generally, Compaq Computer Corp. v. Lapray*, 135 S.W.3d 657

(Tex.2004). Here, there is absolutely *no evidence* that Ackermann relied on any affirmation by Wyeth. Summary Judgment is appropriate for Wyeth on Plaintiff's claim for breach of express warranty without further discussion or analysis. Any claim for a DTPA violation based on breach of an express warranty is also foreclosed. As to a breach of an implied warranty of merchantability under Tex. Bus. Comm.Code section 2.314, no privity of contract is required in a suit for personal injuries, i.e. whether analyzed as horizontal or vertical privity. *See Garcia v. Tex. Instruments,* 610 S.W.2d 456 (Tex.1980). Under the Texas Supreme Court's reasoning in *Garcia,* a person who has not purchased a product can still sue for breach of an implied warranty. However, Wyeth argues that there must still be an underlying sale of goods to create a nexus of liability and trigger applicability of the UCC. In this case, there is no disagreement that the Effexor given to Ackermann was a free sample furnished by Wyeth. Plaintiff argues that there was an "expectation of a sale" or that Ackermann purchased services, and therefore goods, from Dr. Sonn. There is no evidence that Ackermann ever purchased Effexor from Dr. Sonn. No bill has been produced which references any such transaction. In fact, the sample pack notes that the drugs are merely samples and *not for sale.* (Def.'s Mot. Summ. J., Ex. I). Under Texas law, the UCC only applies to transactions involving the sale of goods. Tex. Bus. Comm.Code § 2.102; *Loyd v. ECO Res., Inc.,* 956 S .W.2d 110 (Tex.App.-Houston [14th Dist.] 1997, *no pet.*). Mere promotion of the drugs is not the same as a sale of the drugs. *Yurcic v. Purdue Pharm., L.P.,* 343 F. Supp 2d 386 (M.D.Pa.2004). Moreover, to demonstrate a breach of an implied warranty of merchantability, a plaintiff must establish that the product has a defect which renders it unfit for its ordinary purpose. *Gen.*

Motors v. Garza, 179 S.W.3d 76 (Tex.App.-San Antonio 2005, *no pet.*). To recover damages for breach of an implied warranty of merchantability, a plaintiff must prove there was some defect in the product, that is to say, a condition of the goods that renders them unfit for the ordinary purpose for which they are used because of a lack of something necessary for adequacy. *Otis Spunkmeyer, Inc. v. Blakely*, 30 S.W.3d 678 (Tex.App.-Dallas 2000, *no pet.*). There is no evidence that Effexor is not fit for the ordinary purpose for which it is used, treating depression and general anxiety order. The gravamen of Plaintiff's complaint is that a drug which is normally fit for most patients reacts in a certain way with a small group of patients and therefore increases the risk of suicide. The fact that drugs such as Effexor may cause different reactions in a small group of patients is not tantamount to a holding that the drug is somehow inadequate. Notwithstanding the fact that there was no underlying sale, the Court agrees that to maintain the claim for breach of warranty, notice was required. Tex. Bus. Comm.Code § 2.607(c)(1); *Ibarra v. Nat'l Const. Rentals, Inc.*, 199 S.W.3d 32 (Tex.App.-San Antonio 2006, *no pet.*). Plaintiffs failed to give the requisite notice or to specify why such notice was excused. *U.S. Tire-Tec, Inc.*, 110 S.W.3d at 199. Although the Supreme Court of Texas has not ruled on this specific point, the official comment to section 2.607(c)(1) states *inter alia* that a plaintiff who is a mere beneficiary must notify the seller that an injury has occurred. *See Wilcox v. Hillcrest Mem'l Park of Dallas*, 696 S. W.2d 423 (Tex.App.-Dallas, 1985), *aff'd per curiam*, 701 S.W.2d 842, 843 (Tex.1986). One case has held that under facts similar to this case, furnishing samples of drugs is not a sale which triggers applicability of the UCC. *Allen v. Ortho Pharm. Corp.*, 387 F.Supp. 364 (S.D.Tex.1974). Moreover, sec-

tion 2.315 further contemplates that the "seller" has reason to know any particular purpose for which the goods are required and that the buyer is relying on the seller's skill or judgment to select or furnish suitable goods. Notwithstanding that Ackermann is not a buyer as defined by the Act, there is no showing that he was relying on Wyeth's skill or judgment. To the contrary, he was relying on the skill and judgment of Dr. Sonn. Effexor, like most drugs, is also indicated for other disorders, therefore, it could not be said that Wyeth would have reason to know of the particular purpose for which Effexor would be used. (*See* Def. Mot. Summ. J, Ex. G) (indicates that Effexor can be used to treat depression as well as General Anxiety Disorder). The Court concludes that Plaintiff may not prevail on her claims for breach of an implied warranty as well as an express warranty. For the reasons stated, the Court finds that Defendant is entitled to summary judgment on Plaintiff's claims under the DTPA, as well as breach of express and implied warranties.

Does the Learned Intermediary Doctrine Bar Plaintiff's Relief?

In prescription drug product liability cases, it is reasonable for the manufacturer to rely on the health care provider to pass on its warnings, as the learned intermediary understands the propensities and dangers involved in the use of a given drug, and as the prescriber, he or she stands between the drug and the ultimate consumer. *Wyeth-Ayerst Labs. Co. v. Medrano,* 28 S.W.3d 87 (Tex.App.-Texarkana 2000, *no pet.*). Texas, like most jurisdictions, has adopted section 402A of the RESTATEMENT OF TORTS for product liability claims. *Nobility Homes, Inc., v. Shivers,* 557 S.W.2d 77, 79-80

(Tex.1977). Under that section, "[i]f a product is unreasonably or inherently dangerous, a warning is required." *Gravis v. Parke-Davis & Co.*, 502 S.W.2d 863, 870 (Tex. Civ. App.-Corpus Christi 1973) (*citing* Restatement (Second) of Torts § 402(A) (1965)). Although adequacy as to a warning is generally a question for the fact finder, *Williams v. Upjohn Co.*, 153 F.R.D 110, 114 (S.D.Tex.1994), in cases involving prescription drugs involving the learned intermediary doctrine, when a warning specifically mentions the circumstances complained of, the warning is adequate as a matter of law. *Rolen v. Burrougs Wellcome Co.*, 856 S.W.2d 607, 609 (Tex.App.-Waco 1993); *McNeil v. Wyeth*, 462 F.3d 364 (5th Cir.2006). However, when a warning is either inadequate or misleading, the manufacturer remains liable for injuries sustained by the patient. *McNeil, supra* note 3, at 368. To recover for a failure to warn under this doctrine, Plaintiff must show (1) a defective (or misleading) warning; and (2) the failure to warn was a producing cause of his death. *Porterfield v. Ethicon, Inc.*, 183 F.3d 464, 468 (5th Cir.1999) (citation omitted).

Was the Warning Defective?

Even though the condition or contraindication is mentioned, if the label is misleading as to the risk level for the developing the condition, the warning is defective. *See McNeil, supra.* Plaintiff complains that labeling should have warned about the increased risk of suicide particularly during the early phases of therapy and a need for a wash out period when switching from one SSRI drug to another. The package insert for Effexor notes that "the possibility of a suicide attempt is inherent in depression" and advises close supervision. This is the only mention of a "risk of suicide" contained in the

insert. Defendant relies on the lower court's ruling in *McNeil* for the support of its position that the mere mention of risk suffices. However, the Fifth Circuit has expressly ruled otherwise. Here Plaintiff argues that there should have been some disclosure that for a small subset of patients, suicidal ideation is a risk of taking Effexor. If preemption does not apply, then a fact issue as to the first prong of Plaintiff's *state law* claim on failure to warn exists.

If warnings were inadequate, was such inadequacy a producing cause of Ackermann's death?

Is there a fact issue as to causation? Ackermann took a low dosage of Effexor for a very short period of time, a week or less. The toxicology reports indicate no Effexor (venalafaine) in the post mortem blood sample. The only drug noted is 50 micrograms of citalopram (Celexis) which is consistent with a therapeutic application of the drug. (Def.'s Mot. Summ. J., Ex. J, Barbieri Dep. 9:2-5, June 13, 2006). There is also evidence that Ackermann told one of his treating doctors on the date of his suicide that he was not suicidal. His wife commented to medical personnel that he was on Celexa and had been acting strangely while taking *it*. The package insert does not recommend a wash out period when the drug has been taken for a week or less and Dr. Sonn indicates that no wash out period is indicated for such a low dosage.

There is a dearth of evidence linking Effexor to Ackermann's suicide. The testimony of Dr. Sonn indicates that in spite of the lack of a specific warning as advocated by the Plaintiff, he knew at the time he treated Ackermann that there was some discussion concerning antidepressants having a causative effect in regard to

suicide and that is a risk he considered in prescribing the drug. (Sonn Dep. 38: 1-18). He was also aware that in some patients taking Effexor and other antidepressants attempted suicide and had suicide ideation. (Sonn Dep. 44: 1-7; 45:7-15). Plaintiff claims there is nothing to indicate that Dr. Sonn was then or is now aware what a "legally adequate" warning from Wyeth would have told him. Plaintiff contends that Dr. Sonn did not know at the relevant time *all* the information which would have been included in a proper warning. *See Garside v. Osco Drug, Inc.*, 976 F.2d 77 (1st Cir.1992). Plaintiff argues that this is a case of no warning as opposed to an inadequate warning. Dr. Sonn's supplemental unchallenged affidavit unequivocally states that had the warning been included as advocated by the Plaintiff, nothing would have changed his decision to give Ackermann Effexor. (Declaration of Dr. Sonn). Under Texas law, a plaintiff who complains "that a prescription drug warning is inadequate must also show that the alleged inadeqaucy caused her doctor to prescribe the drug for her." *Porterfield v. Ethicon, Inc.*, 183 F.3d 464, 468 (5th Cir.1999); *accord Stewart v. Janssen Pharm.*, 780 S.W.2d 910, 912 (Tex.App.-El Paso 1989). In other words, a plaintiff must show not only that a warning was inadequate, but that it was a "producing cause" of his injuries. *McNeil, supra* at 372. The doctrine of the "learned intermediary" presupposes that the physician will act as an intermediary. This function includes discussing the cost-benefit ratio with the patient if necessary. Where the physician would have adequately informed a plaintiff of the risks of a disease, had the label been sufficient, but fails to do so on that account, and where the plaintiff would have rejected the drug if informed, the inadequate labeling could be a "producing" cause of the injury because it effectively sabotages the function of the intermediary.

Here, Dr. Sonn testified that he would not have warned Ackermann of the possibility of an increased risk of suicide, primarily because he did not want to suggest to a depressed patient that suicide was an option. (Sonn Dep. 52, 117, 118, 121, 123). Dr. Sonn states he was adequately warned of the risks of Effexor. (Sonn Dep. 54). He stated that he did warn Ackermann about the possible side effect of agitation. He stated that he relied on the label as well as his own experience and knowledge when he prescribed Effexor. He testified that even in light of the new black box warnings on Effexor, he would not approach his warnings any different today. (Sonn Dep. 129, 130).

As previously noted, Dr. Sonn was aware of the fact that suicide attempts had been seen on patients taking Effexor. (Sonn Dep. 44). He was also aware that patients who had taken Effexor had been reported to have suicidal ideations. (Sonn Dep. 45). He was also aware that agitation was a possible side effect. (Sonn Dep. 48). In his declaration, he states that had there been a warning as advocated by the Plaintiff, he would still have prescribed the drug as he did and would not have told Ackermann of warnings related to suicide. In *McNeil*, the Court stated that the treating doctor gave conflicting testimony. He testified that he would have still prescribed the drug at issue but would have warned the patient. On the other hand, he testified that he would not have prescribed the drug had the drug label indicated that use for longer than twelve weeks was contraindicated because risks are significant and the benefits of such continued use have not been demonstrated. Here, Dr. Sonn testified that he would not have warned the patient irrespective of the warning. He gave his medical and professional reason for doing so. Even if Plaintiff's wife could demonstrate that Ackermann would not have taken the drug if

there was an increased risk of suicide associated with a small group of patients, such is not relevant. Dr. Sonn unqualifiedly states that no matter the scope of the warning, he would never have communicated such a warning to Ackermann. Unlike *McNeil*, this is not a case where the learned intermediary fails to pass necessary information to the patient because the manufacturer has understated the degree of risk. The Court finds that Wyeth is entitled to Summary Judgment on the learned intermediary doctrine.

Tex. Civ. Prac. & Rem.Code § 82.007

Wyeth also claims it is entitled to summary judgment based on Tex. Civ. Prac. & Rem.Code Section 82.007. The relevant section reads as follows:

> (a) In a products liability action alleging that an injury was caused by a failure to provide adequate warnings or information with regard to a pharmaceutical product, there is a rebuttable presumption that the defendant or defendants, including a health care provider, manufacturer, distributor, and prescriber, are not liable with respect to the allegations involving failure to provide adequate warnings or information if:
>
> > (1) the warnings or information that accompanied the product in its distribution were those approved by the United States Food and Drug Administration for a product approved under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 301 et seq.), as amended, or Section 351, Public Health Service Act (42 U.S.C. § 262), as amended; or

(2) the warnings provided were those stated in monographs developed by the United States Food and Drug Administration for pharmaceutical products that may be distributed without an approved new drug application.

(b) The claimant may rebut the presumption in Subsection (a) as to each defendant by establishing that:

(1) the defendant, before or after pre-market approval or licensing of the product, withheld from or misrepresented to the United States Food and Drug Administration required information that was material and relevant to the performance of the product and was causally related to the claimant's injury;

(2) the pharmaceutical product was sold or prescribed in the United States by the defendant after the effective date of an order of the United States Food and Drug Administration to remove the product from the market or to withdraw its approval of the product;

(3)(A) the defendant recommended, promoted, or advertised the pharmaceutical product for an indication not approved by the United States Food and Drug Administration;

(B) the product was used as recommended, promoted, or advertised; and

(C) the claimant's injury was causally related to the recommended, promoted, or advertised use of the product;

(4)(A) the defendant prescribed the pharmaceutical product for an indication not approved

by the United States Food and Drug Administration;

(B) the product was used as prescribed; and

(C) the claimant's injury was causally related to the prescribed use of the product; or

(5) the defendant, before or after pre-market approval or licensing of the product, engaged in conduct that would constitute a violation of 18 U.S.C. Section 201 and that conduct caused the warnings or instructions approved for the product by the United States Food and Drug Administration to be inadequate.

Tex. Civ. Prac. & Rem.Code Section 82.007 (2003).

Wyeth claims that it is entitled to judgment based on this presumption statute. Subsection (a) provides that there is a rebuttable presumption that Wyeth is not liable for inadequate warnings when such warnings are approved by the FDA. Wyeth also claims that subparagraph (1) is preempted by the rules and regulations of the FDA relying on the Supreme Court's decision in *Buckman Co. v. Plaintiff's Legal Committee*, 531 U.S. 341 (2001). Wyeth contends that subparagraph (1) is preempted because it is in effect a fraud on the FDA cause of action and must be severed from section 82.007. Plaintiff claims that Wyeth did not furnish evidence of foreign suicides to the FDA and therefore cannot rely on 82.007(a). Plaintiff also argues that the statute is unconstitutional, cannot be severed, and asks the Court to declare the statute unconstitutional.

A presumption is a guide for courts in fixing the burden of producing proof. *See Gen. Motors Corp. v. Saenz*, 873 S.W.2d 353, 359 (Tex.1993). When a presumption arises, it shifts the burden of producing evidence to the

party against whom the presumption operates. *See id.* Once evidence contradicting the presumption has been offered, the presumption disappears and is not weighed or treated as evidence. *Id.* The facts supporting the presumption remain in evidence and can support any reasonable inferences that may be drawn. *Id.* The presumption does not affect the burden of persuasion. *Id.* Statutory presumptions operate in the same manner as presumptions developed through common law. *See, e.g.*, Tex. Prop.Code Ann. § 92.109(d) (Vernon 1984); *Leskinen v. Burford*, 892 S.W.2d 135, 136 (Tex.Civ.App.-Houston [14th Dist.] 1994); *City of Garland v. Dallas Morning News*, 969 S.W.2d 548 (Tex.App.-Dallas 1998), *aff'd*, 22 S.W.3d 351 (Tex.2000). The effect of a statutory presumption is to force the party against whom it operates to produce evidence to negate the presumption. *Balawajder v. Tex. Dept. of Criminal Justice Institutional Div.*, 2006 WL 2192613, at (Tex.App.-Houston [1st Dist.] July 31, 2006, *pet. filed*). In the context of a summary judgment, the party against whom a statutory presumption operates must produce sufficient evidence for the case to proceed to trial. *Id.* The Court disagrees with Wyeth's characterization that subparagraph (1) creates a cause of action of fraud on the FDA. The statute creates no cause of action. In fact, Wyeth has pled the statute as an affirmative defense.

The Supreme Court has held that state law fraud on the FDA claims inevitably conflict with the FDA's responsibility to police fraud consistently with the Administration's judgment and objectives. *Buckman*, 531 U.S. at 345. Two recent circuit court opinions have analyzed a similar state statute and reached opposite results in determining whether the statute is preempted in light of *Buckman*. *See Garcia v. Wyeth-Ayerst Labs.*, 385 F.3d 961 (6th Cir.2004); *Desiano v. Warner-Lamberts & Co.*,

2006 WL 2846454 (2006). Suffice to say, the Court believes that the language of section 82.007(a) creates nothing more than a presumption which the Defendant is free to raise. It does not create a cause of action where none existed before. If Plaintiff comes forward with evidence that the FDA was somehow misled, Plaintiff has merely rebutted a presumption that the manufacturer is not liable. The rebuttal evidence does not establish liability. Such evidence only prevents the manufacturer from obtaining a judgment in its favor without introducing other evidence such as a doctor's testimony that even with a "defective" warning, he still would have prescribed the drug in conformity with his actions without the desired warning. Therefore, the only question is whether Plaintiff has set forth some evidence to prevent Wyeth from obtaining judgment in its favor in light of the statute. Plaintiff argues that foreign incidents were not reported to the FDA. Wyeth argues that foreign incidents need not be reported. The Court declines to recommend summary judgment based on a presumption.

RECOMMENDATION

Based upon the foregoing, it is the Court's recommendation that Wyeth's Motion for Summary Judgment be granted on all grounds except as to the claim for relief under the Tex. Civ. Prac. and Rem.Code Section 82.007.

Within ten (10) days after receipt of the magistrate judge's report, any party may serve and file written objections to the findings and recommendations of the magistrate judge. 28 U.S.C.A. § 636(b)(1)(C).

Failure to file written objections to the proposed findings and recommendations contained in this report within ten days after service shall bar an aggrieved party from

de novo review by the district court of the proposed findings and recommendations and from appellate review of factual findings accepted or adopted by the district court except on grounds of plain error or manifest injustice. *Thomas v. Arn*, 474 U.S. 140, 148 (1985); *Rodriguez v. Bowen*, 857 F.2d 275, 276-77 (5th Cir.1988).

COURT OF APPEALS OF MICHIGAN

Docket No. 267003
June 13, 2006

GERALD DURONIO, Individually and as Class Representative, on behalf of all others similarly situated,

Plaintiff-Appellant,

—v.—

MERCK & COMPANY, INC., Andrea Benjamin, Rubin Benjamin, Angel Klein, Kathy Lindsey, Steve Mogridge, and Fawaz Naja,

Defendants-Appellees.

Before: WHITBECK C.J., and ZAHRA and DONOFRIO, JJ.

[UNPUBLISHED]

PER CURIAM.

Plaintiff appeals as of right from the trial court's order granting summary disposition in favor of defendant Merck & Company, Inc. (Merck), pursuant to MCR 2.116(C)(8). Because the trial court properly determined that plaintiff's common-law fraud claim is, in substance,

a product liability action subject to the absolute defense established by MCL 600.2946(5), and because the trial court correctly determined that the exemption in MCL 445.904(1)(a) applies to plaintiff's MCPA claim, the trial court properly dismissed plaintiff's action, and we affirm.

I. Facts and Proceedings

This action arises from Merck's withdrawal of the prescription drug Vioxx from the market. Plaintiff originally filed this action against Merck and other corporate defendants in November 2004, but plaintiff only named Merck and its alleged pharmaceutical representatives defendants his second amended complaint. Plaintiff alleged that Merck disseminated information to the general public that concealed or downplayed potential cardiovascular risks and falsely implied that Vioxx provided superior pain relief to over-the-counter medications, and that Merck's pharmaceutical representatives misled prescribing physicians regarding the safety of Vioxx for their patients.

Plaintiff sought a refund of the purchase cost of Vioxx, as well as costs and related expenses for a medical consultation recommended by the federal Food and Drug Administration (FDA) and Merck in connection with Merck's voluntary withdrawal of Vioxx from the market. Plaintiff sought recovery based on common-law fraud and the Michigan Consumer Protection Act (MCPA), MCL 445.901 *et seq.* Plaintiff also sought class certification under MCR 3.501 for all Michigan residents residing in Wayne County who have "since the FDA approval of Vioxx in 1999, taken the drug and who have not suffered death, a heart attack, stroke, or other cardiovascular or personal injury or damage to property due

to Vioxx and who have already undergone and/or will undergo the single medical consultation recommended by the FDA, Merck and/or health care professionals."

The trial court dismissed the individual defendants pursuant to the parties' stipulation. The trial court adjourned any decision on plaintiff's request for class certification until after consideration of Merck's motion for summary disposition under MCR 2.116(C)(8). The court subsequently granted Merck's motion, finding that plaintiff's liability theories, in substance, constituted a product liability action as defined in MCL 600.2945(h) of the Revised Judicature Act (RJA) and, therefore, Merck was entitled to immunity from liability under MCL 600.2946(5), given that plaintiff did not plead any constitutional exception to immunity.

II. Standard of Review

We review the interpretation and application of a statute de novo as a question of law. *Health Care Ass'n Workers Compensation Fund v. Director of the Bureau of Worker's Compensation*, 265 Mich.App. 236, 243, 694 N.W.2d 761 (2005).

> The primary goal of judicial interpretation of statutes is to ascertain and give effect to the intent of the Legislature. It is presumed that the Legislature intended the plain and obvious meaning it expressed. If the terms of a statute are ambiguous, judicial construction is appropriate. The Court must apply a reasonable construction that considers the purpose of the statute and the harm it is designed to remedy. The Court must give effect to every word, clause, and sentence, presuming that each is used for a purpose. Likewise, the Court should avoid a

> statutory construction that renders any portion of the statute surplusage or nugatory. The provisions of a statute must be read within the context of the entire statute so as to produce a harmonious and consistent enactment. [*Id.* at 243-244, 694 N.W.2d 761 (citations omitted).]

A trial court's grant of summary disposition is also reviewed de novo. *Maiden v. Rozwood*, 461 Mich. 109, 118, 597 N.W.2d 817 (1999). A motion under MCR 2.116(C)(8) tests the legal sufficiency of a claim based on the pleadings alone. *Id.* at 119-120, 597 N.W.2d 817. "All well-pleaded factual allegations are accepted as true and construed in a light most favorable to the nonmovant." *Id.* at 119, 597 N.W.2d 817. The motion may be granted only if the claim is so clearly unenforceable as a matter of law that no factual development could possible justify recovery. *Id.* Although the trial court granted summary disposition under MCR 2.116(C)(8), subrule (C)(7) is the appropriate subrule to apply where a claim is barred by immunity granted by law. An appellate court may review a trial court's decision under the correct rule. *Spiek v. Dep't of Transportation*, 456 Mich. 331, 337, 572 N.W.2d 201 (1998). In reviewing a motion under subrule (C)(7), the allegations in a complaint are accepted as true, unless contradicted by proofs submitted by the parties.[1] *Maiden, supra* at 119, 597 N.W.2d 817.

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[1] Regardless of which subrule applies, the result in this case would be the same because we are presented only with a question of law to be determined solely from the pleadings.

III. Analysis

Plaintiff argues that the trial court erred in characterizing his action as a product liability action within the meaning of MCL 600.2945(h). In general, tort law has provided the source for a product liability action. See *Neibarger v. Universal Cooperatives, Inc.*, 439 Mich. 512, 486 N.W.2d 612 (1992), and *Prentis v. Yale Mfg. Co.*, 421 Mich. 670, 682-683, 365 N.W.2d 176 (1984). In the case of an individual consumer, "the remedy for products liability is not premised upon an agreement between the parties, but derives either from a duty imposed by law or from policy considerations which allocate the risk of dangerous and unsafe products to the manufacturer and seller rather than the consumer."[2] *Neibarger, supra* at 523, 486 N.W.2d 612.

As added by 1978 PA 495, MCL 600.2946 established certain evidentiary standards for a product liability action. Evidence of compliance with governmental or industry standards was admissible to determine if the standard of care was met. *Taylor v. Gate Pharmaceuticals*, 468 Mich. 1, 6, 658 N.W.2d 127 (2003). At that time, MCL 600.2945 defined a "[p]roducts liability action" as "an action based on *any* legal or equitable theory of liability brought for on or account of death *or injury to person or property* caused by or resulting from the manufacture . . . marketing, advertising, packaging, or labeling of a product or a component of a product" (emphasis added). Later, 1995 PA 161, modified the definition section to use the phrase "injury to person or

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[2] The existence of a duty is also a necessary element for a fraud claim where it is claimed that information was suppressed. See *Hord v. Environmental Research Institute of Michigan*, 463 Mich. 399, 412, 617 N.W.2d 543 (2000); *Bergen v. Baker*, 264 Mich.App. 376, 382, 691 N.W.2d 770 (2004).

damage to property." The legislature replaced the word "any" preceding "legal or equitable theory" with the word "a."

The legislature substantially revised MCL 600.2945 to include a number of definitions, but retained the "injury to person or damage to property" phrase in the definition of "product liability action ." 1995 PA 249.

> "Product liability action" means an action based on a legal or equitable theory of liability brought for the death of a person or for *injury to a person or damage to property* caused by or resulting from the production of a product. [MCL 600.2945(h) (emphasis added).]

The word "product" is defined separately as "any and all component parts to a product," MCL 600.2945(g), and "production" is defined as "manufacture, . . . warning, instructing, marketing, selling, advertising, packaging, or labeling," MCL 600.2945(i).

The legislature also substantially modified MCL 600.2946 through its adoption of 1995 PA 249. Subject to two exceptions, MCL 600.2946(5) now establishes an absolute defense for drug manufacturers and sellers in a product liability action, where the drugs complied with FDA standards and labeling. *Taylor, supra* at 6-7, 658 N.W.2d 127. Under MCL 600.2946(5), "a product that is a drug is not defective or unreasonably dangerous, and the manufacturer or seller is not liable, if the drug was approved for safety and efficacy by the United States food and drug administration, and the drug and its labeling were in compliance with the United States food and drug administration's approval at the time the drug left the control of the manufacturer or seller. . . ."

Thus, plaintiff's common-law fraud claim is subject to the absolute defense established by MCL 600.2946(5) if

it falls within the definition of "product liability action" in MCL 600.2945(h). Although we must accept the factual allegations in plaintiff's second amended complaint as true for purposes of deciding this issue, *Maiden, supra* at 119, 597 N.W.2d 817, we are not bound by a party's choice of labels for its action because this would put form over substance. See *Kostyu v. Dep't of Treasury*, 170 Mich.App. 123, 130, 427 N.W.2d 566 (1988). Plaintiff's mere allegation that he is not pursuing a product liability action is not controlling.

Because plaintiff did not allege any injury to his person, the trial court could only find a legal or equitable theory falling within the scope of MCL 600.2945(h) if plaintiff's action could be characterized as one for "damage to property" caused by or resulting from the production of Vioxx. We reject Merck's claim that plaintiff failed to preserve this particular issue for appeal. The fact that an appellant did not fully brief and argue an issue in the trial court, or that it cites authority on appeal that the trial court did not consider, does not preclude the appellant from raising the issue on appeal. *Steward v. Panek*, 251 Mich.App. 546, 554, 652 N.W.2d 232 (2002). Furthermore, we may consider the issue because it presents a question of law. *Id.*

Merck attempts to equate "damage to property" with "economic loss." We are not persuaded by Merck's assertions, because had the Legislature intended this, it would have used the phrase "economic loss," which is defined in MCL 600.2945(c), in place of "damage to property" in MCL 600.2945(h). The phrase "damage to property" is not defined in the statute so we turn to dictionary definitions to determine its plain meaning, keeping in mind the context in which it is used. *Griffith v. State Farm Mut. Automobile Ins. Co.*, 472 Mich. 521, 533, 697 N.W.2d 895 (2005); *Wessels v. Garden Way,*

Inc., 263 Mich.App. 642, 649, 689 N.W.2d 526 (2004). The *Random House Webster's College Dictionary* (1997) defines "property" as "1. that which a person owns; the possession or possessions of a particular owner. 2. goods, land, etc., considered as possessions. 3. a piece of land or real estate. 4. ownership; right of possession, enjoyment or disposal, esp. of something tangible. . . ." Also instructive is 63C Am Jur 2d, Property, § 1, which broadly defines "property" as encompassing the bundle of rights associated with an object:

> As a matter of legal definition, "property" refers not to a particular material object but to the right and interest in an object. "Property" in a thing does not consist merely in its ownership or possession, but also in the lawful, unrestricted right of its use, enjoyment, and disposal. In its precise legal sense, property is nothing more than a collection of rights.
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> * * *
>
> In contemporary jurisprudence, "property" refers to the various incorporeal ownership rights in a res, such as the right to possess, to enjoy the income from, to alienate, or to recover ownership from one who has improperly obtained title to the res, as well as to the actual physical object of these rights. [(Internal footnotes and citations omitted.)]

The word "damage" is defined in *Random House Webster's College Dictionary* (1997) as "injury or harm that reduces value, usefulness, etc.", while "damages" refers to "the estimated money equivalent for loss or injury sustained." In *Universal Underwriters Ins. Co. v. Kneeland*, 464 Mich. 491, 496-497, 628 N.W.2d 491 (2001), our Supreme Court indicated that "damages" could refer to any harm caused to a third-party person or property,

or losses for which there is a legal right to recovery, when finding ambiguity in a courtesy car agreement in which the renter agreed to assume all responsibility for damages while the vehicle was in his possession. In *Smolen v. Dahlmann Apartments, Ltd.*, 127 Mich.App. 108, 114-115, 338 N.W.2d 892 (1983), this Court found that the ordinary meaning of "damage" included injury to something, when construing a statutory provision providing that a renter's security deposit may only be used to reimburse the landlord for "actual damages to the rental unit. . . ." This Court determined that a rental unit that required cleaning was not damaged. *Id.* at 115, 338 N.W.2d 892.

MCL 600.2945(h) does not use the word "damages," but rather requires an "action based on a legal or equitable theory of liability brought for the death of a person or for injury to a person *or damage to property* caused by or resulting from the production of a product." Examined in context, we reject plaintiff's claim that "damage to property" only encompasses physical damage to property. The phrase is broad enough to include both physical damage to an object and injury or harm to rights or interests associated with an object, so long as the damage is caused by or results from the production of the product. Cf. *Holtz v. Bd. of Comm'rs of Elkhart Co.*, 560 N.E.2d 645, 647 (Ind., 1990) ("damage to property" in definition of "loss" under Indiana's Tort Claims Act includes injury to property rights and interests); see also *Indiana Dep't of Transportation v. Shelly & Sands, Inc.*, 756 N.E.2d 1063, 1077 (Ind.App., 2001) (claim against state for corporate lost profits and additional costs subject to Indiana's Tort Claims Act if it sounds in tort).

The fact that the alleged injury in this case is in the form of monetary loss does not preclude application of MCL 600.2945(h). Money itself is a form of property,

Garris v. Bekiares, 315 Mich. 141, 148-149, 23 N.W.2d 239 (1946), and a consumer's expenditure of money for overvalued goods can constitute an injury to property. Cf. *Reiter v. Sonotone Corp.*, 442 U.S. 330, 99 S.Ct. 2326, 60 L.Ed.2d 931 (1979) (in antitrust action, an injury to "property" occurred when retail purchasers purchased consumer goods artificially inflated by anti-competitive conduct).

Plaintiff asserts that he is seeking rescission for a fraudulently induced purchase contract. In light of plaintiff's failure to adequately brief any basis for a rescission remedy against Merck, we deem this issue abandoned. An appellant may not merely announce a position and leave it to this Court to discover and rationalize its basis. *Peterson Novelties, Inc. v. City of Berkley*, 259 Mich.App. 1, 14, 672 N.W.2d 351 (2003). While rescission of a contract is an appropriate remedy for fraud in the inducement, plaintiff's request for a refund of the purchase price of Vioxx is nothing more than a claim against a noncontracting party for monetary losses measured by the cost to purchase Vioxx. Further, plaintiff presented the claim as arising from misrepresentations and omissions, and denied that the alleged concealed risks of using Vioxx ever materialized for him, but it is clear that the safety and efficacy of Vioxx is essential to his monetary loss claim.

Because plaintiff brought the claim for damage to property (money) caused by or resulting from the production (marketing, selling, advertising, packaging, or labeling) of Vioxx, plaintiff's pleaded common-law fraud claim for a refund of the cost of purchasing Vioxx is, in substance, a product liability action within the meaning of MCL 600.2945(h). Assuming for purposes of our review that plaintiff's request to have Merck pay for a medical consultation is actionable in tort, plaintiff's

alleged loss of a right or interest in money to obtain a medical consultation constitutes damage to property within the meaning of MCL 600.2945(h). Any additional claim for lost income or expenses to obtain the medical consultation is merely a pecuniary loss flowing from that injury. *Citizens for Pretrial Justice v. Goldfarb,* 415 Mich. 255, 268, 327 N.W.2d 910 (1982).

The trial court properly determined that plaintiff's common-law fraud claim is, in substance, a product liability action subject to the absolute defense established by MCL 600.2946(5). Plaintiff raises an argument concerning the validity of MCL 600.2946(5), but because it is not set forth in the statement of the questions presented, plaintiff failed to preserve this argument for our consideration. MCR 7.212(C)(5); *City of Lansing v. Hartsuff,* 213 Mich.App. 338, 351, 539 N.W.2d 781 (1995). Although we are empowered to overlook plaintiff's improper presentation of this argument, *Health Care Ass'n Workers Compensation Fund, supra* at 243, 694 N.W.2d 761, we are not persuaded that the Sixth Circuit Court of Appeals improperly decided in *Garcia v. Wyeth-Ayerst Laboratories,* 385 F.3d 961 (C.A.6, 2004), that the fraud-on-the-FDA exception in MCL 600.2946(5)(a) is partially preempted by federal law. Although we are not bound to follow the decision in *Garcia,* see *Abela v. Gen. Motors Corp.,* 469 Mich. 603, 607, 677 N.W.2d 325 (2004), we agree with its holding that the fraud-on-the FDA exception is preempted by federal law unless the FDA itself determines that it was defrauded. Examined in this context, plaintiff has not established that the trial court erred in granting summary disposition in favor of Merck with respect to plaintiff's claim alleging common-law fraud. In light of this decision, we decline to address the parties' remaining arguments regarding whether there are alternative grounds

for affirming the trial court's order of summary disposition with respect to the common-law fraud claim.

Next, we turn to plaintiff's Michigan Consumer Protection Act (MCPA) claim. MCL 445.901 *et seq.* Although the trial court did not decide whether plaintiff pleaded a cognizable claim under the MCPA, we will overlook this preservation requirement to consider this issue of law. *Miller v. Inglis* 223 Mich.App. 159, 168, 567 N.W.2d 253 (1997). This claim is based on the same factual allegations and seeks the same remedy as plaintiff's common-law fraud claim. Both claims rely on alleged misrepresentations related to the safety and efficacy of Vioxx. The MCPA protects Michigan's consumers by prohibiting various methods, acts, and practices in trades or commerce. *Slobin v. Henry Ford Health Care,* 469 Mich. 211, 215, 666 N.W.2d 632 (2003); *Zine v. Chrysler Corp.*, 236 Mich.App. 261, 275, 600 N.W.2d 384 (1999). The legislature intended the MCPA to provide an "enlarged remedy for consumers who are mulcted by deceptive business practices." *Dix v. American Bankers Life Assurance Co.*, 429 Mich. 410, 417, 415 N.W.2d 206 (1987). It authorizes class actions for damages by a person who suffers a loss and by the attorney general, MCL 445.910(5) and MCL 445.911(3). The MCPA's exemptions are established by MCL 445.904, and MCL 445.916 states that "[t]his act shall not affect any other cause of action which is available."

We must give a reasonable construction to a statute that considers its purpose and the harm that it is designed to remedy. *Health Care Ass'n Workers Compensation Fund, supra* at 244, 694 N.W.2d 761. The Legislature is presumed to be aware of existing statutes when enacting new laws. *Inter Cooperative Council v. Dep't of Treasury,* 257 Mich.App. 219, 227, 668 N.W.2d 181 (2003). Based on the clear and unambiguous lan-

guage of the MCPA, the MCPA does not affect a product liability action, as defined in MCL 600.2945(h), if it is available to a plaintiff. The RJA, while using broad language to define a "product liability action" as an "action based on a legal or equitable theory of liability . . ." in MCL 600.2945(h), likewise does not bar a MCPA claim. To hold otherwise would, in effect, render the ability of a person and the attorney general to pursue a class action for damages under the MCPA a nullity, where the claim is based on deceptive advertising practices for a product, because the definition of "production" in the RJA includes "advertising." MCL 600.2945(i). A court should avoid a construction that renders any portion of a statute surplusage or a nugatory. See *Health Care Ass'n Workers Compensation Fund, supra* at 244, 694 N.W.2d 761; *Inter Cooperative Council, supra* at 225, 668 N.W.2d 181.

MCL 445.904(1)(a) provides that the MCPA does not apply to "[a] transaction or conduct specifically authorized under laws administered by a regulatory board or officer acting under statutory authority of this state or the United States." The focus of this statutory provision is not the specific misconduct alleged by a plaintiff, but whether the general transaction is authorized by law. *Smith v. Globe Life Ins. Co.*, 460 Mich. 446, 464-465, 597 N.W.2d 28 (1999); see also *Newton v. Bank West*, 262 Mich.App. 434, 438-440, 686 N.W.2d 491 (2004) (holding that the MCPA exemption applies to a residential mortgage transaction made by federal savings bank under laws administered by regulatory board or its officers); *Kraft v. Detroit Entertainment, LLC*, 261 Mich.App. 534, 540-542, 683 N.W.2d 200 (2004) (MCPA exemption applies to the operation of slot machines regulated and authorized by state statute).

The Food, Drug, and Cosmetic Act of 1938 (FDCA), 21 USC 301 *et seq.*, governs drug marketing, manufacturing, and distribution, and vests the FDA with powers to enforce regulations. *Thompson v. Western States Medical Ctr.*, 535 U.S. 357, 361, 122 S.Ct. 1497, 152 L.Ed.2d 563 (2002). The regulations implementing the FDCA are extensive and detailed, and specifically regulate prescription drug advertising. *Bober v. Glaxo Wellcome PLC*, 246 F.3d 934 (C.A.7, 2001); 21 CFR 202.1. Because the general marketing and advertising activities underlying plaintiff's MCPA claim are authorized and regulated under laws administered by the FDA, the exemption in MCL 445.904(1)(a) applies to plaintiff's MCPA claim. The trial court properly dismissed plaintiff's MCPA claim.

In light of this holding, we do not address the parties' arguments concerning whether plaintiff sufficiently pleaded the requisite "loss" for purposes of MCL 445.911(2) and (3) to bring an individual or class action for damages.

Affirmed.

UNITED STATES DISTRICT COURT
E.D. PENNSYLVANIA

No. 04-CV-05987-LDD
Oct. 11, 2005

MARY HENDERSON,

—v.—

MERCK & CO., INC., *et al.*

James J. McHugh, Michael S. Katz, The Beasley Firm LLC, Philadelphia, PA, for Mary Henderson.

Heather Reardon Olson, Stefanie J. Fogel, Raymond M. Williams, DLA Piper Rudnick Gray Cary LLP, Joshua G. Schiller, Dechert, Philadelphia, PA, for Merck & Co., Inc., et al.

MEMORANDUM OPINION

DAVIS, J.

Presently before the Court are defendants Pfizer, Inc., Pharmacia & Upjohn LLC, and G.D. Searle, Inc.'s ("defendants") motion for judgment on the pleadings

(Doc. No. 19), plaintiff's brief in opposition to the motion (Doc. No. 23), defendants' reply brief thereto (Doc. No. 27), and plaintiff's memorandum sur-reply in opposition to plaintiff's motion for judgment on the pleadings (Doc. No. 28). For the following reasons, this Court grants defendants' motion for judgment on the pleadings.

I. Factual and Procedural History

This action arises from alleged injuries suffered by plaintiff Mary Henderson ("plaintiff"), a resident of Michigan, from the ingestion of two prescription drugs: Bextra and Vioxx. (*See* Compl., at ¶¶ 46-50, 73-77). Plaintiff filed a complaint against defendants on December 22, 2004. (*Id.*, at ¶ 4). On April 12, 2005, the Judicial Panel on Miltidistrict Litigation entered a Conditional Transfer Order, which transferred plaintiff's Vioxx claims to the Eastern District of Louisiana. Plaintiff's Bextra-related claims remain in this forum.

The Food and Drug Administration ("FDA") approved Bextra on November 16, 2001. (*See* FDA Approval Package, attached as Ex. A to Def. Br.). Plaintiff's complaint alleges that defendant G.D. Searle, Inc. ("Searle") and defendant Pharmacia & Upjohn LLC ("Pharmacia") were initially responsible for testing, developing, manufacturing, distributing, licensing, labeling, and marketing Bextra. (*Id.*, at ¶¶ 29-30, 22-26). On April 26, 2003, defendant Pfizer, Inc. ("Pfizer") allegedly acquired the assets and liabilities of Pharmacia and Searle, continuing the business of testing, developing, manufacturing, distributing, licensing, labeling, and marketing Bextra. (*Id.*, at ¶¶ 38-39).

Plaintiff alleges that she was prescribed and began taking Bextra in 2002, and that the continued consumption of Bextra caused severe injuries, including blood

clots on December 23, 2002 and a heart attack in March 2003. (*See* Compl., at ¶¶ 67-72). Plaintiff's complaint alleges seven theories of liability against defendants: (i) negligence; (ii) products liability-defective design; (iii) products liability-failure to warn; (iv) breach of express warranty; (v) fraudulent misrepresentation; (vi) fraud; and (vii) negligent misrepresentation. Each theory pertains to the allegedly unsafe manner in which Bextra was designed, developed, manufactured, distributed, marketing, promoted, labeled, or represented.

On July 21, 2005, defendants filed a motion for judgment on the pleadings. (Doc. No. 19). Plaintiff filed a response on August 5, 2003. (Doc. No. 23). Both parties filed additional briefs in support of their respective positions. (Doc. No. 27-28).

II. Judgment on the Pleadings

Rule 12(c) of the Federal Rules of Civil Procedure permits a party to move for judgment on the pleadings after the closing of all pleadings. *See* Fed.R.Civ.P. 12(c). The standard for a Rule 12(c) motion for judgment on the pleadings is similar to that of a Rule 12(b)(6) motion to dismiss. *See, e.g., Turbe v. Government of Virgin Islands*, 938 F.2d 427, 428 (3d Cir.1991). Therefore, like a Rule 12(b)(6) motion, a Rule 12(c) motion may be granted only when it clearly appears that the opposing party can prove no set of facts in support of the claim which would entitle her to relief. *See Conley v. Gibson*, 355 U.S. 41, 45-46, 78 S.Ct. 99, 2 L.Ed.2d 80 (1957); *Robb v. City of Philadelphia*, 733 F.2d 286, 290 (3d Cir.1984). In applying this standard, this Court "must take all the well pleaded allegations as true, construe the complaint in the light most favorable to the plaintiff, and determine whether, under any reasonable reading of the pleadings, the plaintiff may be entitled to relief." *Col-*

burn v. Upper Darby Township, 838 F.2d 663, 665-66 (3d Cir.1988).

A. Pennsylvania's Choice-of-law Methodology

The resolution of defendants' Rule 12(c) motion requires a determination of which law applies to the various claims in plaintiff's complaint. In determining the applicable law, a court must apply the choice-of-law principles of the state in which the district court sits. *Klaxon Co. v. Stentor Electric Mfg. Co.,* 313 U.S. 487, 496, 61 S.Ct. 1020, 85 L.Ed. 1477 (1941). Under Pennsylvania's choice of law rules, a court must first determine whether a conflict exists. *See, e.g., Ghallagher v. Medical Research Consultants,* 2004 WL 2223312, at n. 15 (E.D.Pa. Oct.1, 2004). If a conflict exists, the court must then characterize the "conflict" between the proposed competing bodies of law. *See, e.g., Garcia v. Plaza Oldsmobile Ltd.,* 421 F.3d 216, 220 (3d Cir.2005). Finally, if the conflict is characterized as a true conflict, the court must analyze which state has the greater interest in the application of its law. *See, e.g., Cipolla v. Shaposka,* 439 Pa. 563, 267 A.2d 854, 855 (Pa 1970).

1. Existence of Conflict

As a threshold question, a conflict exists if the application of the proposed laws would lead to different results. *See, e.g., Pilot Air Freight Corp. v. Sandair, Inc.,* 118 F.Supp.2d 557, 561 n. 3 (E.D.Pa.2000). If the application of the proposed laws would not lead to different results, the court need only apply forum law. *Id.* ("Where the different laws do not product different results, courts presume that the law of the forum state shall apply."). If it would lead to different results, the court must characterize the type of conflict.

2. Characterization

In order to determine what type of "conflict" exists, the court must perform an "interest analysis" of the policies of the interested states and then characterize the relationship between the policies and the factual predicate of the action as a true conflict, a false conflict, or an unprovided-for case. *See, e.g., Budget Rent-A-Cary System, Inc. v. Chappell,* 407 F.3d 166, 170 (3d Cir.2005).

a. True Conflict

A true conflict exists "when the government interests of multiple jurisdictions would be impaired if their law were not applied." *Lacey v. Cessna Aircraft Co.,* 932 F.2d 170, 187 n. 15 (3d Cir.1991). If a true conflict exists, Pennsylvania's choice of law rules requires the "application of the law of the state having the most significant contacts or relationships with the particular issue." *See Chappell,* 407 F.3d at 170 (internal quotations omitted).

b. False Conflict

A false conflict exists "if only one jurisdiction's governmental interests would be impaired by the application of the other jurisdiction's law." *Lacey,* 932 F.2d at 187. In the event of a false conflict, Pennsylvania's choice of law rules require the application of the law of the only interested state. *See Chappell,* 407 F.3d at 170.

c. Unprovided For Situation

Finally, an "unprovided for" situation arises when "no jurisdiction's interests would be impaired if its laws were not applied." *Id.* An unprovided-for case triggers the law of the place of the wrong. *Id.*

3. Most Significant Contacts Analysis

If a true conflict exists, a court must apply the law of the state with the greatest interest, based upon an analysis of which state has the most significant contacts with the particular issue. *See, e.g., Garcia,* 421 F.3d at 220. In making this determination, courts look to the following contacts as outlined in § 145 of the Restatement (Second) of Conflicts: (i) the place where the injury occurred; (ii) the place where the conduct causing the injury occurred; (iii) the domicile, residence, nationality, place of incorporation, and place of business of the parties; and (iv) the place where the relationship between the parties is centered. *See, e.g., Flamer v. New Jersey Transit Bus Operations, Inc.,* 414 Pa.Super. 350, 607 A.2d 260, 264 (Pa.Super.Ct.1992); *Laconis v. Burlington County Bridge Comm'n,* 400 Pa.Super. 483, 583 A.2d 1218, 1222-23 (Pa.Super.Ct.1990). These contacts should be analyzed qualitatively, rather than quantitatively, in light of the "policies and interests underlying the particular issue before the court." *See, e.g., Norman v. Johns-Manville Corp.,* 406 Pa.Super. 103, 593 A.2d 890, 893 (Pa.Super.Ct.1991).

B. Michigan Law Applies To All Claims

Defendants contend that Pennsylvania's choice of law analysis requires application of Michigan law. (*See* Def. Br., at 7). Defendants first contend that Pennsylvania law and Michigan law conflict, as they lead to difference outcomes. (*Id.*). Defendants then argue that this conflict is a false conflict, requiring application of Michigan law, because Pennsylvania's interest in applying its own law would be unimpaired if the Court, applying Michigan law, refused to allow a Michigan citizen to recover against drug manufacturers that are not residents of

Pennsylvania. (*Id.*, at 7-8, 593 A.2d 890). Furthermore, to the extent that a true conflict exists, defendants contend that Michigan is the state with the most significant relationship with plaintiff's claims. (*Id.*).

In response, plaintiff argues that defendants have failed to address the litany of additional states with interests in applying their laws to plaintiff's claims. (*See* Pl. Br., at 7). Plaintiff then submits that no conflict exists between Michigan, Pennsylvania, New York, New Jersey, and Delaware law because the different laws would not yield different results; indeed, according to plaintiff, Michigan law does not provide immunity to drug manufacturers who receive FDA approval when this approval is based upon fraudulent representations, and Pennsylvania, New York, New Jersey, and Delaware law permit all product liability claims against drug manufacturers for the manufacture, sale, or marketing of an unsafe product. (*Id.*, at 3, 593 A.2d 890). Plaintiff argues, however, that even if application of the different laws would produce different results, a false conflict exists. According to this logic, Pennsylvania, New York, New Jersey, or Delaware law should apply because, as compared to Michigan, which lacks an interest in the imposition of its law against out-of-state drug manufacturers, such as the defendants, these states have an interest in imposing liability on in-state manufacturers of defective drugs. (*Id.*, at 4-7, 593 A.2d 890).

1. A conflict exists between Michigan law, Pennsylvania law, and the laws of New York and New Jersey.[1]

Under Pennsylvania's choice of law analysis, this court must first determine whether a conflict exists. *See, e.g., McCrossan v. Wiles,* 2004 WL 1925057, at (E.D.Pa. Aug.30, 2004). A conflict exists if the laws of the states with applicable interests yields different results. *See, e.g., Travelers Cas. and Sur. Co. v. Irex Corp.,* 2002 WL 32351176, at (E.D.Pa. May 31, 2002).

Michigan is the state of plaintiff's residence, the location where plaintiff purchased, ingested, and was prescribed Bextra, and the situs of plaintiff's injuries. (*See* Compl., at ¶¶ 4, 67-72).[2] Michigan contains a statute that immunizes drug manufacturers from civil liability in a "product liability action" for injuries related to drugs that have been approved by the FDA, unless the FDA makes an express finding of fraud or bribery on the part of a defendant in the application process. *See* Mich. Comp. Laws Ann. § 600.2946(5); *Garcia v. Wyeth-Ayerst Laboratories,* 385 F.3d 961, 967 (6th Cir.2004) (finding § 600.2946(5)(a)-(b) unconstitutional in certain contexts). A product liability action is defined as "an action based on a legal or equitable theory of liability brought

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[1] No party seeks to apply different laws to different issues. Indeed, both plaintiff and defendants group plaintiff's claims together in determining which state law to apply, conducting a choice of law analysis as to all of plaintiff's claims collectively, rather than conducting a separate choice of law analysis as to each claim individually.

[2] Plaintiff alleges that she was a resident of Michigan at all times pertinent to this litigation. (*See* Compl., at ¶ 4). Furthermore, plaintiff fails to challenge defendant's recitation of the factual contacts between this litigation and the state of Michigan. (*See* Def. Br., at 8).

for the death of a person or for injury to a person or damage to property caused by or resulting from the production of a product." *Id.* § 600.2945(g); 11 Mich. Pl. & Pr. § 81A:3 (2d ed.2005).

Pennsylvania is the forum for this action and is a state in which all the defendants allegedly do business. (*See* Compl., at ¶¶ 8, 18, 24, 31, 40).[3] Pennsylvania does not contain a statutory scheme analogous to that of Michigan. However, the Pennsylvania Supreme Court has declared that strict liability does not lie against manufacturers or sellers of pharmaceutical drugs, reasoning that pharmaceutical drugs are "unreasonably unsafe" within the meaning of comment k to § 402A of the Restatement (Second) of Torts. *See, e.g., Parkinson v. Guidant Corp.*, 315 F.Supp.2d 741, 748 n. 6 (W.D.Pa.2004) (granting summary judgment to manufacturer of prescription medical device on strict products liability claims because Pennsylvania Supreme Court "unambiguously has held that § 402A strict liability does *not* apply in any way to prescription drugs"); *Hahn v. Richter*, 543 Pa. 558, 673 A.2d 888, 890-891 (Pa.1996); *Anderson v. Wyeth*, 2005 WL 1383174, at , 7 (Pa. Com. Pl. Phila. Co. June 7, 2005) (pharmaceutical drug cases under Pennsylvania law can only be based upon negligence and not strict liability). On the other hand, however, Pennsylvania law, unlike Michigan law, permits negligence claims and other forms of non-strict liability tort claims against drug manufacturers. *See Hahn*, 673 A.2d at 891 (acknowledging validity of negligence claim

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[3] Plaintiff also contends that defendant Merck is a Pennsylvania corporation. (*See* Pl. Br., at 7). However, the claims against Merck pertain only to Vioxx and have been severed and transferred to the Eastern District of Louisiana. Furthermore, plaintiff alleges in her complaint that Merck is a New Jersey corporation. (*See* Compl., at ¶ 5).

against drug manufacturer for failure to warn of dangers associated with pharmaceutical drugs); *Baldino v. Castagna*, 505 Pa. 239, 478 A.2d 807, 810 (Pa.1984) (acknowledging validity of negligent marketing theory of liability against drug manufacturer).

New Jersey is the state in which Pharmacia and Searle maintain their principal places of business, and, according to plaintiff, are incorporated. (*See* Compl., at ¶¶ 21, 29). New York is the state in which Pfizer maintains its principal place of business, and, according to plaintiff, is incorporated. (*Id.*, at ¶ 37, 478 A.2d 807). These states, like Pennsylvania, lack statutes immunizing drug manufacturers from strict products liability. Unlike Pennsylvania, however, the laws of New Jersey and New York permit, in various forms, strict product liability claims against manufacturers and sellers of prescription drugs. For instance, New Jersey performs a risk-utility analysis on a case-by-case basis to determine whether strict product liability claims may be brought against manufacturers of prescription drugs, reasoning that comment k to § 402A of the Restatement (Second) of Torts does not immunize all drug manufacturers from strict liability. *Feldman v. Lederle Laboratories*, 97 N.J. 429, 479 A.2d 374, 441-449 (N.J.1984) ("we are of the opinion that generally the principles of strict liability are applicable to manufacturers of prescription drugs"). New York permits, at the very least, failure to warn strict product liability claims against manufacturers of prescription drugs, subject to various affirmative defenses. *See, e.g., Martin v. Hacker*, 83 N.Y.2d 1, 607 N.Y.S.2d 598, 628 N.E.2d 1308, 1311 (N.Y.1993) (permitting strict liability failure to warn claim to go forward against manufacturer of pharmaceutical drugs, subject to affirmative defense of adequate warnings); *Militrano v. Lederle Laboratories*, 3 Misc.3d 523, 769 N.Y.S.2d 839,

846-847 (N.Y.Sup.Ct.2003) (suggesting that New York Court of Appeals would bar design defect liability claim against drug manufacturer). Both states also permit non-strict liability claims against drug manufacturers. *See, e.g., Rubel v. Eli Lilly & Co.*, 681 F.Supp. 151, 153 (S.D.N.Y.1987) (describing procedural history of case in which drug manufacturer found liable under New York law for negligently failing to test product); *Feldman v. Lederle Laboratories*, 125 N.J. 117, 592 A.2d 1176, 1182-1183 (N.J.1991) (implicitly acknowledging validity of negligence, gross negligence, strict liability, and breach of implied and express warranty claims against drug manufacturer under New Jersey law); *Salva v. Blum*, 277 A.D.2d 985, 716 N.Y.S.2d 527, 528 (N.Y.App.Div.2000) (permitting negligence and strict products liability, breach of warranty, and failure to warn claims against drug manufacturer under New York law for defective manufacture, distribution, testing, and marketing of drugs).

In summary, the application of Michigan law, which bars (subject to certain exceptions) all product liability claims against manufacturers of FDA-approved drugs, of Pennsylvania law, which bars strict product liability claims against manufacturers of pharmaceutical drugs but which permits negligence and other tort theories of product liability relief against such manufacturers, and of New York and New Jersey law, which permit strict liability and non-strict liability claims against drug manufacturers, would lead to different results. A conflict between these laws therefore exists.[4]

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[4] Plaintiff also claims that Delaware has an interest in this litigation by virtue of defendants' incorporation in that state. (*See* Pl. Br., at 7-8). However, plaintiff's complaint alleges that defendants are incorporated in New York and New Jersey, as compared to Delaware. (*See* Compl., at ¶¶ 21, 29, 37); *Bryson v. Brand Insulations, Inc.*, 621

2. An actual conflict exists between Michigan law, Pennsylvania law, and New York and New Jersey law.

Because a conflict exists between Michigan law, Pennsylvania law, and the laws of New York and New Jersey, the Court now characterizes the type of conflict between these competing bodies of law. *See, e.g., Cipolla,* 267 A.2d at 855.

This Court finds that a true conflict exists between Michigan law, Pennsylvania law, and New Jersey and New York law. First, Michigan's interest would be impaired by the application of another state's law. Although plaintiff contends that Michigan "would have no interest in denying a Michigan citizen the opportunity to recover for wrongdoing [allegedly] committed by a number of out-of-state corporations," this Court disagrees. (*See* Pl. Br., at 7). Part of the rationale behind the Michigan statutory scheme was the reduction of costs of FDA-approved pharmaceutical drugs for Michigan cit-

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F.2d 556, 559 (3d Cir.1980) (court must take all well-pleaded allegations as true in deciding motion for judgment on pleadings). Furthermore, to the extent that plaintiff's allegations are factually incorrect and defendants are actually incorporated in Delaware, the Court notes that the additional evaluation of the applicability of Delaware law, which is substantially similar to that of Pennsylvania on the issues raised in this litigation, would not change the ultimate outcome of this choice-of-law analysis. *See, e.g., LeJeune,* 85 F.3d at 1071 ("Delaware law, however, does not recognize strict products liability based on the rationale that such claims are preempted by the Uniform Commercial Code."); *Cline v. Prowler Idus. of Maryland, Inc.,* 418 A.2d 968, 974-975 (Del.1980) (refusing to recognize strict products liability in all cases involving sales transactions because recognition of such a theory of liability would be an impermissible form of judicial legislation in direct conflict with Delaware legislature's adoption of the Uniform Commercial Code). Michigan would still have a greater interest than Delaware in applying its own law, for the same reasons expressed in Section II-B-3 of this opinion.

izens and the encouragement of pharmaceutical companies to do business in Michigan. *See Garcia*, 385 F.3d at 967 (in enacting § 600.2946(5), "Michigan legislature was concerned that unlimited liability for drug manufacturers would threaten the financial viability of many enterprises and could add substantially to the cost and unavailability of many drugs"). To the extent that application of another state's law would yield a judgment against defendants, all of whom are national pharmaceutical companies who sell pharmaceutical drugs to Michigan residents, Michigan's interest in preventing the "passing-on" of the costs of pharmaceutical liability judgments onto its citizenry in the form of expensive and potentially unaffordable drug prices would be impaired. *See, e.g., LeJeune v. Bliss-Salem, Inc.*, 85 F.3d 1069, 1072 (3d Cir.1996) (state could have a host of reasons for limiting products liability, including encouraging economic activity in state and lowering costs to consumers). Moreover, M.C.L.A. § 600.2946(5) does not limit itself to intra-territorial conflicts between Michigan residents and that small sub-set of pharmaceutical companies who are incorporated, or who have a primary places of business, in Michigan. Consequently, allowing a Michigan citizen to prevail against a pharmaceutical company that does business in the state of Michigan would contradict one of the primary objectives of the statute.[5]

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[5] Michigan's interest in protecting its citizens from "pass-on" costs associated with all product liability judgments against manufacturers and sellers of FDA-approved drugs readily distinguishes this case from the Third Circuit's decision in *Lacey v. Cessna Aircraft Company*, 932 F.2d 170 (3d Cir.1991), upon which plaintiff relies. (*See* Pl. Br., at 6-7). In *Lacey*, the Third Circuit performed a preliminary choice-of-law analysis as part of a broader *forum non conveniens* determination, and suggested that Pennsylvania law, which

This Court also finds that Pennsylvania's interests would be impaired by the application of Michigan law. Although Pennsylvania does not permit strict product liability actions against drug manufacturers, Pennsylvania does permit negligence claims against such manufacturers. This jurisprudence encourages drug manufacturers who do business in Pennsylvania to exercise reasonable care to produce safe products, while recognizing that it is unfair to penalize manufacturers of inherently unsafe products, such as pharmaceutical drug companies, for the mere act of designing, manufacturing, and labeling such products. Pennsylvania has alleged that all defendants do business in Pennsylvania. (*See* Compl., at ¶¶ 24, 26-28, 32, 34-36, 40, 43-45). Consequently, although Pennsylvania's interest in deterring misconduct by drug manufacturers is weakened by virtue

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recognizes strict liability against manufacturers of defective aircraft products, rather than British Columbia law, which recognizes only negligence liability against such manufacturers, would probably apply to plaintiff's claim. *Id.* at 188. The Third Circuit reasoned that only a false conflict existed because the sole interest behind British Columbia law—"fostering industry within its borders"—would not be impaired by the application of Pennsylvania strict products liability law against a defendant that did not possess an industrial operation in British Columbia. *Id.*

Unlike the situation in *Lacey*, however, the Michigan legislature chose to eliminate all product liability actions against drug manufacturers, including negligence claims, in part to make prescription drugs available and affordable to Michigan residents. In other words, the purpose of M.C.L.A. § 600.2946(5)(a) is both to encourage industry within Michigan's borders and to protect the welfare of Michigan residents. The latter interest is clearly implicated by the factual circumstances behind plaintiff's claims, and, unlike British Columbia's interest in *Lacey*, Michigan's interest would be impaired by the application of laws that recognize the validity of either strict product or negligence theories of liability against drug manufacturers for injuries arising from the production of FDA-approved drugs.

of the facts that none of the defendants are citizens of Pennsylvania for purposes of diversity jurisdiction [6] and because the plaintiff is a resident of Michigan, Pennsylvania still retains a valid interest in deterring drug manufacturers who do business in Pennsylvania from negligently designing, marketing, and labeling prescription drugs. This interest would be impaired by the application of Michigan law.

The Court further finds that the interests of New York and New Jersey, where defendants maintain their principal places of business and are allegedly incorporated, would be impaired by the application of Michigan law. These states do not *per se* exempt drug manufacturers from strict liability, negligence, or fraud claims for injuries caused by FDA approved drugs. *See, e.g., Martin,* 607 N.Y.S.2d 598, 628 N.E.2d at 1311 (strict product liability claim lies under New York law against drug manufacturers who fail to properly prepare drug and to provide adequate warnings); *Feldman,* 479 A.2d at 449 (no *per se* public policy exception under New Jersey law for design defect and failure to warn strict product liability claims against drug manufacturers, as such manufacturers should assume liability for product that is "not fit, suitable, or safe for its intended use"). To apply Michigan law would therefore impair the interests of these states in deterring resident drug manufacturers from producing and disseminating unsafe products, regardless of where the injury takes place. *See LeJeune,* 85 F.3d at 1071 (purpose of strict product liability law is for state "to protect its citizens from defective products and to encourage manufacturers to produce safe prod-

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[6] For purposes of diversity jurisdiction, a corporation is a citizen of any state by which it has been incorporated and of any state in which the corporation has its principal place of business. *See* 28 U.S.C. § 1332(c)(1).

ucts"); *Lacey*, 932 F.2d at 188 (application of law that recognizes only negligence principles would impair competing state's interest in applying its strict products liability law to deter instate manufacturer from producing defective products).

In summary, this Court concludes that a true conflict exists between Michigan law, Pennsylvania law, and the laws of New York and New Jersey, finding that the objectives of each state's law, as made relevant through the various factual circumstances of this litigation, would be impaired by the application of the law of a different state.

3. Michigan has the most significant contacts with the litigation.

The Court now determines which state has the most significant contacts with the litigation. In making this determination, this Court must look to an array of factors: (i) the place where the injury occurred; (ii) the place where the conduct causing the injury occurred; (iii) the domicile, residence, nationality, place of incorporation and place of business of the parties; and (iv) the place where the relationship, if any, between the parties is centered. *See* Restatement (Second) of Conflicts § 145. These contacts only become important when they relate to the "policies and interests underlying the particular issue before the court." *Cipolla*, 267 A.2d at 856. The focus of the analysis therefore must be on the qualitative, rather than the quantitative, weight of the contacts. *Id.*

Applying these factors, it is clear that Michigan has the most significant qualitative contacts with this litigation. Plaintiff is a resident of Michigan. *See, e.g., Normann v. Johns-Manville Corp.*, 406 Pa.Super. 103, 593 A.2d 890, 894-895 (Pa.Super.Ct.1991) (applying law of New York, rather than law of Pennsylvania, to product

liability claims because decedent resided in New York during time of exposure to asbestos). She purchased the drugs in Michigan, thereby making Michigan the center of the parties' relationship. Presumably, a physician located in Michigan prescribed the drugs at issue. Furthermore, plaintiff's reliance on defendant's representations concerning Bextra occurred in Michigan. Perhaps most importantly, plaintiff's injuries occurred in Michigan. *See, e.g., LeJeune,* 85 F.3d at 1072 (placing great emphasis on location of accident in product liability action in determining state with greatest interest in having its law applied); *Laconis v. Burlington County Bridge Comm'n,* 400 Pa.Super. 483, 583 A.2d 1218, 1223 (Pa.Super.Ct.1990) ("in an action for personal injuries, the law of the state where the injury occurred normally determines the rights and liabilities of the parties, unless another state, applying the contacts test, has a more significant relationship to the occurrence and parties"). Based upon these contacts, the Court finds that Michigan has a strong interest in applying its law to ensure that Michigan residents, including plaintiff, are not burdened with excessively high payments for prescription drugs, indeed, that such drugs remain financially available for all Michigan citizens, even if that means immunizing non-resident pharmaceutical companies who do business in Michigan from product-related claims brought by a Michigan resident for injuries suffered in Michigan.

In comparison, the only contact between New York and New Jersey and this litigation is defendants' residence in these states; and the only contacts between Pennsylvania and this litigation is Pennsylvania's forum status and defendants' distribution of Bextra into the Pennsylvania marketplace. The importance of these contacts is diluted by the fact that the remaining relevant

events took place in Michigan. Indeed, because plaintiff is a Michigan resident, because plaintiff purchased, was prescribed, and ingested Bextra within Michigan's borders, and because plaintiff allegedly suffered injuries in Michigan, the interests of Pennsylvania, New York, and New Jersey in applying their product liability laws to such extraterritorial conduct lose vigor. *See, e.g., Laconis,* 583 A.2d at 1223 (applying Pennsylvania law over New Jersey law when Pennsylvania was the place of Pennsylvania citizen's injury, while New Jersey's only contacts with litigation were defendant's incorporation under laws of that state and defendant's transaction of business there); *Lewis v. Bayer,* 2004 WL 1146692, at 78-79 (C.C.Pl.Phila.Co. Nov. 18, 2004) (applying law of states where class members reside, took Baycol, and suffered injuries, as compared to law of state where defendant does business, to negligence claim against drug manufacturers arising from manufacturing, labeling, marketing, and ingestion of Baycol).[7] Furthermore, the Court notes that plaintiff's failure to provide any analysis as to why the interests of Pennsylvania, New York, or New Jersey are more significant than the interests of Michigan highlights the merit in this Court's conclusion that Michigan law should apply.

In summary, the Court finds that Michigan has the greatest interest in applying its product liability laws to injuries suffered in Michigan by a Michigan resident based upon the sale, prescription, and consumption of a pharmaceutical drug in Michigan. This determination comports with the expectations of the parties and the policies of all interested states.

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[7] The strength of Pennsylvania's interest in deterring the negligence of drug manufacturers is particularly diluted because, according to plaintiff's complaint, defendants are not citizens of the Commonwealth of Pennsylvania.

B. Application of Michigan law

In determining whether plaintiff's claims may proceed under Michigan law, the Court must perform a two-part analysis. First, the Court must determine whether plaintiff's claims fall under the definition of "product liability action" within the meaning § 600.2946(5)(a), which immunizes drug manufacturers and sellers of FDA approved drugs from civil liability for physical injuries arising from the production of the drug. Second, the Court must determine whether plaintiff meets any of the exceptions to this statutory scheme.

1. Civil Immunity

Subject to various exceptions, M.C.L.A. § 600.2946(5) prohibits all "product liability actions" against a manufacturer or seller of a prescription drug if the drug was approved by the FDA and if the drug was in compliance with the FDA's approval at the time the drug left the control of the manufacturer or seller. *See* Mich. Compl. Laws Ann. § 600.2946(5). The Michigan statutory scheme defines product liability actions to include any action "based on a legal or equitable theory of liability brought for the death of a person or for injury to a person . . . caused by or resulting from the production of a product." *Id.* § 600.2945(h). Production is defined broadly to include "manufacture, construction, design, formulation, . . . warning, instructing, marketing, selling, advertising, packaging, or labeling." *Id.* § 600.2945(i).

The statutory definition of "product liability action" covers each of plaintiff's claims against defendants. First, each claim seeks damages for plaintiff's physical injuries, including blood cots and her ultimate heart attack in 2003. (*See* Compl., at ¶¶ 119, 131, 145, 153,

164, 176, 186). Second, each claim attributes these injuries to the "production of a product." *See* Mich. Comp. Laws § 600.2946(5). For instance, plaintiff's negligence, defective design, failure to warn, and breach of warranty claims are covered by this definition of "production," as these claims expressly seek damages for the manner in which Bextra was designed, manufactured, marketing, advertised, distributed, promoted, tested, and sold. (*Id.*, at ¶¶ 113, 116, 123-124, 127- 128, 135-137, 149-150). Furthermore, plaintiff's fraud, fraudulent misrepresentation, and negligent misrepresentation claims emanate from the manner in which defendants sold, advertised, and marketed Bextra to the medical community and the public at large. (*Id.*, at ¶¶ 157-158, 168-170, 180-182).[8] Consequently, unless plaintiff meets an exception to the grant of immunity in § 600.2946(5), plaintiff's claims against defendants fail as a matter of law under Michigan law.

2. Exceptions

The grant of immunity in M.C.L.A. § 600.2946(5) contains two exceptions. These exceptions apply when a seller or manufacturer: (a) intentionally withholds or misrepresents information concerning the drug to the FDA in violation of the Food Drug and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 *et seq.*, and the drug would not have been approved if the information was submitted; or (b) makes an illegal payment to an official or employee of the FDA for the purpose of securing or

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[8] Plaintiff does not argue that, under Michigan law, only certain claims in the complaint meet the definition of "product liability action." Instead, plaintiff's sole argument as to the survival of plaintiff's claims under Michigan law concerns the applicability of the exception in § 600.2946(5)(a).

maintaining approval of the drug. *See* Mich. Com. Laws Ann. § 600.2946(5)(a)-(b).

Standing alone, the text of the statutory exceptions to M.C.L.A. § 600.2946(5) would arguably permit plaintiff's claims to survive, as plaintiff's complaint alleges that defendants falsely and fraudulently represented to the "medical community" that Bextra "had been tested and found to be safe and effective for the treatment of pain." (*See* Pl. Compl., at ¶ 157). At the very least, the possibility of the applicability of the textual exceptions to M.C.L.A. § 600.2946(5) would permit plaintiff to take additional discovery on the issue of whether defendants misrepresented material information to the FDA during the approval process.

This analysis, however, is complicated by the Sixth Circuit's recent decision in *Garcia v. Wyeth-Ayerst Laboratories,* 385 F.3d 961 (6th Cir.2004). In *Garcia,* the Sixth Circuit concluded that the exceptions of § 600.2946(5)(a)-(b) are preempted by the FDCA, unless the FDA itself makes an explicit finding that a defendant engaged in bribery or fraud during the drug application process. *Id.* at 967. The Sixth Circuit, in reaching this decision, relied heavily upon the Supreme Court opinion of *Buckman Co. v. Pls. Legal Comm.,* 531 U.S. 341, 350, 121 S.Ct. 1012, 148 L.Ed.2d 854 (2001). Therefore, in order to determine whether plaintiff's allegations trigger the exceptions to Michigan's product liability statute, this Court must analyze: (i) the Supreme Court's decision in *Buckman;* (ii) the Sixth Circuit's decision in *Garcia* against the backdrop of *Buckman;* and (iii) the impact of the principles announced in *Buckman* and *Garcia* on the availability of M.C.L.A. § 600.2946(5)(a) to plaintiff's claims.

a. *Buckman*

In *Buckman*, the Supreme Court declared that state-law fraud-on-the-FDA claims conflict with, and are therefore impliedly preempted by, the FDCA and its allocation of regulatory powers to the FDA. *Buckman Co.*, 531 U.S. at 348. The Court first reasoned that fraud-on-the-FDA claims would undermine the responsibility of the FDA to "police fraud" in accordance with its judgment and objectives, as established through the FDCA. *Id.* at 350. The Court then noted the practical problems in recognizing the validity of state-law fraud-on-the-FDA claims, reasoning that such claims would discourage medical device manufacturers from seeking approval of devices with potentially beneficial uses that the FDA does not regulate. *Id.* at 350-351. The Court further predicted that the threat of liability from such state-law claims would require applicants to submit a "deluge" of gratuitous information during the approval process, thereby delaying the approval process and, in turn, impeding competition among predicate devices and slowing beneficial products from reaching the marketplace. *Id.* Consequently, based upon these considerations, the Court concluded that the prospect of state law litigation in fifty states against manufacturers of medical devices would "exert an extraneous pull on the scheme established by Congress," and, thus, that such claims are preempted by the FDCA. *Id.*, at 353.

b. *Garcia*

Seizing upon the holding in *Buckman*, the Sixth Circuit recently found that the exceptions in M.C.L.A. § 600.2946(5)(a) and (b) were preempted by the FDCA. *Garcia*, 385 F.3d at 967. The *Garcia* Court rejected any difference in the potentially deleterious impact on the

FDA's statutory responsibilities between state-law fraud-on-the-FDA claims and a state-law statutory scheme that immunizes drug manufacturers unless fraud-on-the-FDA exists. *Id.* at 966. According to the *Garcia* Court, permitting such a fraud exception to M.C.L.A. § 600.2946(5) would "raise the same inter-branch-meddling concerns that animated *Buckman.*" *Id.* The exceptions to M.C.L.A. § 600.2946(5), as written, therefore conflicted with the supremacy clause.

Nonetheless, the *Garcia* Court refused to find that the exceptions to M.C.L.A. § 600.2946(5) were unconstitutional in all settings. *Id.* Specifically, the *Garcia* Court acknowledged that when the FDA itself determines that fraud or bribery has been committed during the regulatory approval process, the federalism and inter-branch intrusion concerns that motivated *Buckman* were not implicated. *Id.* The *Garcia* Court therefore interpreted M.C.L.A. § 600.2946(5) to offer blanket immunity to drug manufacturers and sellers for injury caused by a drug that had been approved by the FDA, unless the FDA itself issues findings that a party committed fraud or engaged in bribery during the regulatory approval process. *Id.* at 966-967. Because plaintiff failed to offer evidence of such FDA findings, the *Garcia* Court affirmed the district court's grant of summary judgment to the defendant drug manufacturer.

At least one other federal court has used the *Garcia* rationale to invalidate a similar pro-plaintiff exception to a state statutory scheme that provides (a form of) liability immunity to drug manufacturers under certain conditions. In *Kobar v. Novartis Corporation,* 378 F.Supp.2d 1166 (D.Ariz.2005), the United Stated District Court for the District of Arizona found that A.R.S. § 12-701(B), an exception to A.R.S. § 12-701(A), which immunizes drug manufacturers and sellers from punitive

damages in product liability suits when the FDA approved the drug that allegedly caused the harm, was impliedly preempted by provisions of the FDCA that regulate the drug approval process. *Id.* at 1168, 1174. The exception to the statutory scheme permitted a plaintiff to defeat punitive damages immunity by proving, by clear and convincing evidence, that the defendant "withheld from or misrepresented to the [Food and Drug] administration information known to be material and relevant to the harm which the plaintiff allegedly suffered." *Id.* at 1168.

The *Kobar* Court applied the principles of *Buckman* and *Garcia*. First, the Court rejected plaintiff's distinction between the federalism concerns posed by recognition of a fraud-on-the-FDA state claim and those generated by a plaintiff's burden to prove that a manufacturer withheld "material and relevant" information from the FDA before or after making the drug available for public use. *Id.* at 1172. In so doing, the *Kobar* Court found that both evidentiary burdens posed the same horizontal and vertical governmental conflicts, as state courts would be placed "in the uncomfortable and difficult position of having to answer the question of what role, if any, the allegedly withheld information would have played in the FDA's complicated approval process." *Id.* at 1173. Second, the Court noted the problematic practical consequences that could stem from upholding the exception to § 12-701(A), such as delaying the application process and the public's access to potentially revolutionary drugs, belying the FDA's capacity to police and deter fraud, and increasing the costs of pharmaceutical drugs. *Id.* at 1173-1174. Finally, like the *Garcia* Court, the *Kobar* Court concluded that § 12-701(B) was unconstitutional in all situations except when the FDA

makes a finding that is has been defrauded. *Id.* at 1174-1175.

c. Availability of Statutory Exceptions to M.C.L.A. § 600.2946(5) in Light of *Buckman* and *Garcia*

This Court follows the holdings of *Buckman* and *Garcia*, and finds that M.C.L.A. § 600.2946(5)(a) and (b) are preempted by the FDCA in most situations. The Court also finds that plaintiff's claims do not fall within any of the circumstances in which M.C.L.A. § 600.2946(5)(a) and (b) are not preempted. Indeed, plaintiff has not alleged that the FDA made a finding of fraud or that bribery was involved in the FDA approval of Bextra. Finally, because plaintiff's complaint is devoid of allegations to trigger these exceptions, discovery on this issue would be futile. Accordingly, this Court holds as a matter of law that § 600.2946(5)(a) and (b) are inapplicable to plaintiff's claims.

3. Conclusion

This Court finds that Michigan law applies to all of plaintiff's claims. This Court further finds that M.C.L.A. § 600.2946(5) requires dismissal of plaintiff's claims. Specifically, the Court finds that defendants meet the elements of immunity in M.C.L.A. § 600.2946(5) with respect to plaintiff's claims and that the exceptions to this grant of immunity, in light of *Garcia*, are inapplicable. An appropriate Order follows.

ORDER

AND NOW, this 11th day of October 2005, upon consideration of defendants Pfizer, Inc. ("Pfizer"), Pharmacia & Upjohn LLC ("Pharmacia"), and G.D. Searle,

Inc.'s ("Searle") (collectively referred to as "defendants") motion for judgment on the pleadings (Doc. No. 19), plaintiff's brief in opposition to the motion (Doc. No. 23), defendants' reply brief thereto (Doc. No. 27), and plaintiff's memorandum sur-reply in opposition to defendants' motion for judgment on the pleadings (Doc. No. 28), it is hereby ORDERED that defendants' motion (Doc. No. 19) is GRANTED. It is hereby further ORDERED that all of plaintiff's claims against defendants are dismissed; and that Pfizer, Pharmacia, and Searle are therefore dismissed as parties to this litigation.

UNITED STATES DISTRICT COURT
M.D. TENNESSEE
NASHVILLE DIVISION

No. 3:06-MD-1760
Feb. 27, 2007

In re AREDIA AND ZOMETA PRODUCTS LIABILITY LITIGATION

Adam J. Berger, Schroeter, Goldmark & Bender, Seattle, WA, Andy L. Allman, Clinton L. Kelly, Fred Dulin Kelly, Kelly, Kelly & Allman, Hendersonville, TN, Annesley H. Degaris, Cory, Watson, Crowder & Degaris, P.C., Birmingham, AL, Bart T. Valad, John Vecchione, Law Firm of Bart T. Valad, PLLC, Fairfax, VA, C. Patrick Flynn, Michael K. Radford, Flynn & Radford, Brentwood, TN, Christopher A. Seeger, Seeger Weiss LLP, Newark, NJ, Crymes G. Pittman, Joseph E. Roberts, Jr., Robert G. Germany, Pittman, Germany, Roberts & Welsh, LLP, Jackson, MS, Daniel A. Osborn, Philip J. Miller, Russel H. Beatie, Beatie & Osborn, New York, NY, Dara Lovitz, Gregory S. Spizer, Anapol, Schwartz, Weiss, Cohan, Feldman & Smalley, P.C., Philadelphia, PA, David R. Gronbach, Moynahan & Minnella, LLC, Waterbury, CT, Fred Cromwell Isaac, Foerster, Isaac & Yerkes, P.A., Michael E. Seelie, Michael E.

Seelie, P.A., Myers Carroll Cayer, Terrell, Hogan, Jacksonville, FL, Howard K. Coates, Jr., Mary F. April, The Coates Law Firm, Wellington, FL, James W. Dodson, Law Offices of James W. Dodson, Clearwater, FL, Jason Mark, Jerrold S. Parker, Melanie H. Muhlstock, Parker & Waichman, LLP, Great Neck, NY, John O. Threadgill, Threadgill Law Firm, Knoxville, TN, John S. Wallach, St. Louis, MO, John C. Weisensell, Bernlohr & Wertz, Akron, OH, Kermit J. Morgan, Santa Monica, CA, Lewis T. Stoneburner, Michael G. Phelan, Wallace B. Wason, Jr., Cantor Arkema, P.C., Richmond, VA, Michael T. Mullen, Peter D. Tarpey, Paul B. Episcope, LLC, Chicago, IL, Pamela J. Diedrich, Roy Lenard Mason, Mason, Cawood & Hobbs, PA, Annapolis, MD, Paul Anthony Daniels, Teague, Rotenstreich & Stanaland, Greensboro, NC, Peter H. Gunst, Astrachan, Gunst & Thomas, P.C., Baltimore, MD, Richard C. Bennett, Bennett, Johnson & Galler, Oakland, CA, Robert W. Briley, Briley Law Group, PLLC, Nashville, TN, Thomas Q. Keefe, Jr., Belleville, IL, Thomas E. Rubbert, Law Offices of Thomas E. Rubbert, Pasadena, CA, William P. Woods, Woods & Woods, LLP, Evansville, IN, Windle Turley, Law Offices Of Windle Turley, P.C., Dallas, TX, Scott J. Eldredge, Burg, Simpson, Eldredge, Hersh & Jardine, P.C., Englewood, CO, for Plaintiff.

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A. Bruen, Farella, Braun & Martel, L.L.P., San Francisco, CA, Edward W. Gerecke, Penelope A. Dixon, Carlton Fields, P.A., Tampa, FL, Edward S. Sledge, III, Frederick G. Helmsing, Jr., MCdowell, Knight, Roedder & Sledge, LLC, Mobile, AL, Eric J. Buhr, Roxanne M. Wilson, Reed Smith LLP, Los Angeles, CA, Ethan D. Stein, Gibbons, Del Deo, Dolan, Griffinger & Vecccione, New York, NY, James B. King, Keefe, King & Bowman, P.S., Spokane, WA, Jim C. Curtis, Mark N. Osborn, Kemp Smith LLP, El Adam J. Berger, Schroeter, Goldmark & Bender, Seattle, WA, Andy L. Allman, Clinton L. Kelly, Fred Dulin Kelly, Kelly, Kelly & Allman, Hendersonville, TN, Annesley H. Degaris, Cory, Watson, Crowder & Degaris, P.C., Birmingham, AL, Bart T. Valad, John Vecchione, Law Firm of Bart T. Valad, PLLC, Fairfax, VA, C. Patrick Flynn, Michael K. Radford, Flynn & Radford, Brentwood, TN, Christopher A. Seeger, Seeger Weiss LLP, Newark, NJ, Crymes G. Pittman, Joseph E. Roberts, Jr., Robert G. Germany, Pittman, Germany, Roberts & Welsh, LLP, Jackson, MS, Daniel A. Osborn, Philip J. Miller, Russel H. Beatie, Beatie & Osborn, New York, NY, Dara Lovitz, Gregory S. Spizer, Anapol, Schwartz, Weiss, Cohan, Feldman & Smalley, P.C., Philadelphia, PA, David R. Gronbach, Moynahan & Minnella, LLC, Waterbury, CT, Fred Cromwell Isaac, Foerster, Isaac & Yerkes, P.A., Michael E. Seelie, Michael E. Seelie, P.A., Myers Carroll Cayer, Terrell, Hogan, Jacksonville, FL, Howard K. Coates, Jr., Mary F. April, The Coates Law Firm, Wellington, FL, James W. Dodson, Law Offices of James W. Dodson, Clearwater, FL, Jason Mark, Jerrold S. Parker, Melanie H. Muhlstock, Parker & Waichman, LLP, Great Neck, NY, John O. Threadgill, Threadgill Law Firm, Knoxville, TN, John S. Wallach, St. Louis, MO, John C. Weisensell, Bernlohr & Wertz, Akron, OH, Kermit J.

Morgan, Santa Monica, CA, Lewis T. Stoneburner, Michael G. Phelan, Wallace B. Wason, Jr., Cantor Arkema, P.C., Richmond, VA, Michael T. Mullen, Peter D. Tarpey, Paul B. Episcope, LLC, Chicago, IL, Pamela J. Diedrich, Roy Lenard Mason, Mason, Cawood & Hobbs, PA, Annapolis, MD, Paul Anthony Daniels, Teague, Rotenstreich & Stanaland, Greensboro, NC, Peter H. Gunst, Astrachan, Gunst & Thomas, P.C., Baltimore, MD, Richard C. Bennett, Bennett, Johnson & Galler, Oakland, CA, Robert W. Briley, Briley Law Group, PLLC, Nashville, TN, Thomas Q. Keefe, Jr., Belleville, IL, Thomas E. Rubbert, Law Offices of Thomas E. Rubbert, Pasadena, CA, William P. Woods, Woods & Woods, LLP, Evansville, IN, Windle Turley, Law Offices Of Windle Turley, P.C., Dallas, TX, Scott J. Eldredge, Burg, Simpson, Eldredge, Hersh & Jardine, P.C., Englewood, CO, for Plaintiff. Alicia M. Wyler, Stephen E. Matasich, Day Ketterer, Ltd., Canton, OH, Andrew L. Colocotronis, Baker, Donelson, Bearman, Caldwell & Berkowitz, PC, Knoxville, TN, Catherine R. Baumer, Donald W. Fowler, Heather A. Pigman, Jeffrey A. Dickey, Joe G. Hollingsworth, Katharine R. Latimer, Robert E. Johnston, Spriggs & Hollingsworth, Washington, DC, Dan E. Labelle, Halloran & Sage, LLP, Westport, CT, Deirdre C. Gallagher, Thomas W. Hayde, Jr., Spencer, Fane, Britt & Browne, LLP, Clayton, MO, Derrick K. Watson, James A. Bruen, Farella, Braun & Martel, L.L.P., San Francisco, CA, Edward W. Gerecke, Penelope A. Dixon, Carlton Fields, P.A., Tampa, FL, Edward S. Sledge, III, Frederick G. Helmsing, Jr., McDowell, Knight, Roedder & Sledge, LLC, Mobile, AL, Eric J. Buhr, Roxanne M. Wilson, Reed Smith LLP, Los Angeles, CA, Ethan D. Stein, Gibbons, Del Deo, Dolan, Griffinger & Vecccione, New York, NY, James B. King, Keefe, King & Bowman, P.S., Spokane, WA, Jim

C. Curtis, Mark N. Osborn, Kemp Smith LLP, El Paso, TX, Michael L. McCluggage, Sarah Olson, Wildman Harrold, Chicago, IL, Peter G. Pappas, Nexsen, Pruet, Adams & Kleemeier, PLLC, Greensboro, NC, Yanika C. Smith, Baker, Donelson, Bearman, Caldwell & Berkowitz, PC, Nashville, TN, for Defendant.

MDL Clerk of Court, MDL Judicial Panel, Washington, DC, pro se.

ORDER

TODD J. CAMPBELL, United States District Judge.

This documents relates to ALL CASES.

Pending before the Court is a Report and Recommendation of the Magistrate Judge (Docket No. 293), concerning Case No. 3:06-1166, to which no Objections have been filed. The Court has reviewed the Report and Recommendation and the file. The Report and Recommendation is adopted and approved.

Accordingly, the Consolidated Motion for Remand filed by Plaintiffs Francine Scalamoni, Joseph Scalamoni, George Davis and Helen Davis in Case No. 3:06-1166 (Exhibit 7 to Docket No. 15) is GRANTED, and the causes of action of Plaintiffs Francine Scalamoni, Joseph Scalamoni, George Davis and Helen Davis are remanded to the New Jersey state court. Plaintiffs' Motion for Attorney's Fees After Improvident Removal (also Exhibit 7 to Docket No. 15 in Case No. 3:06-1166) is DENIED.

IT IS SO ORDERED.

REPORT AND RECOMMENDATION

JOE B. BROWN, United States Magistrate Judge.

Related to Case No. 3:06-cv-01166.

TO: The Honorable Todd J. Campbell

I. INTRODUCTION

Plaintiffs, Francine Scalamoni, Joseph Scalamoni, George Davis and Helen Davis (hereinafter "Plaintiffs") have filed a Consolidated Motion and Memorandum of Law for Remand and Attorney's Fees After Improvident Removal (Case No. 3:06-1166, Docket Entry 15, Exhibit 7). This Consolidated Motion was referred to the undersigned for Report and Recommendation. (Case No. 3:06-MDL-1760, Docket Entry 217).

For the reasons stated below, the Magistrate Judge recommends that the Plaintiffs' Consolidated Motion for Remand be **GRANTED** and that Plaintiffs' causes of action be **REMANDED** to New Jersey state court. Further, the Magistrate Judge recommends that Plaintiffs' request for attorneys' fees be **DENIED.**

II. BACKGROUND

Plaintiffs are residents of New Jersey. (Case No. 3:06-1166, Docket Entry 15, Exhibit 4, Page 2, ¶¶ 2-5). Defendant is a corporation incorporated in Delaware with its principal offices located in New Jersey. (Case No. 3:06-1166, Docket Entry 15, Exhibit 2, Page 2, ¶ 6). The complaint was filed on August 25, 2006, in the Superior Court of New Jersey. (Case No. 3:06-1116, Docket Entry 15, Exhibit 4). The complaint alleges that Plaintiffs' developed severe osteonecrosis of the jaw (hereinafter "ONJ") caused by their use of the drug Aredia© and/or the drug Zometa© (hereinafter "the medi-

cations"). Plaintiffs request both compensatory and punitive damages under the New Jersey Products Liability Act as well as under common law theories of strict liability, negligence, breach of warranty (express and implied) and loss of consortium. In Count IV, Plaintiffs allege that Defendant negligently failed to warn Plaintiffs and their medical providers of the risks involved in using the medications. Additionally, Plaintiffs allege that Defendant failed to meet the standard of care set by the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 301, et. seq (hereinafter "FDCA"), regarding labeling. Plaintiffs contend that the labeling lacked adequate information on the use of the drugs, failed to provide adequate warnings regarding the use of the drugs, was misleading and promotional. Further, Plaintiffs contend that Defendant's acts above constitute an adulteration and/or misbranding as defined by FDCA § 331. Specifically, paragraph 45 alleges that:

> As a result of Defendant's negligence and the violations of the statutes and regulations listed above[1], Plaintiffs suffered injuries and damages as alleged herein. As a direct and proximate result of Defendant's failure to warn, Plaintiff's have developed osteonecrosis of the jaw, are at risk of developing other diseases, and have suffered compensatory damages and are entitled to punitive damages in the amounts to be proven at trial.

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[1] In addition to 21 U.S.C. § 331, Plaintiffs allege that Defendant violated the Sherman Food, Drug and Cosmetic Law and the following federal statutes regarding the labeling issues described above: 21 C.F.R Section 201.26(a), (b) and (d), 21 C.F.R. 201.57(e) and (f)(1) and (2). (Case No. 3:06-1166, Docket Entry 15, Exhibit 4, Page 11, ¶ 42).

Defendant filed a timely petition for removal from the state court to the United States District Court of New Jersey alleging that the Court has federal question jurisdiction under 28 U.S.C. § 1331.[2] (Case No. 3:06- 1166, Docket Entry 15, Exhibit 3). To support the removal, Defendant propounded three arguments. First, citing *Grable & Sons Metal Prods., Inc. V. Darue Eng'g & Mfg,*[3] Defendant advanced that Plaintiffs' claims require resolution of substantial federal issues, even though a federal cause of action is not directly listed in the complaint, because Plaintiffs allege that the FDA-approved labeling of the medications was inadequate, false and misleading and that the medications were not adequately tested. Second, Defendant puts forth that the Court has federal question jurisdiction under the doctrine of complete preemption because "Congress has so thoroughly and intentionally regulated the marketing and promotion of prescription medications that any challenge to such marketing and promotion necessarily states a federal cause of action: violation of the FDCA and its implementing regulations." Third, and lastly, Defendant argues that Plaintiffs' claim for punitive damages also raises a substantial federal question because New Jersey's product liability punitive damages statute incor-

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[2] Interestingly enough, there are still several cases pending against the Defendant involving these specific medications which are currently pending in New Jersey state court. Therefore, to some extent, the argument about remand of this one case is a bit of a tempest in a teapot.

[3] 545 U.S. 308, 125 S.Ct. 2363, 2366-67, 162 L.Ed.2d 257 (2005). Additionally, Defendant cites an FDA memorandum regarding the approval of product labeling, conflicting state law claims related to the adequacy of prescription drug warnings, and preemption arguments. *See* Requirements on Content and Format of Labeling for Human Prescription Drug and Biologic Products, 71 Fed.Reg. 3922, 3934, 39935 (Jan. 24, 2006).

porates federal law by providing for a fraud-on-the-FDA prerequisite.[4]

Plaintiffs filed the instant motion to remand to the state forum on the ground that federal court lacks subject matter jurisdiction as each of the Plaintiffs' seven claims in their well pleaded complaint are based on state statutory or common law. (Case No. 3:06-1166, Docket Entry 15, Exhibit 7). Further, Plaintiffs request their attorneys' fees and costs. Shortly after filing the instant motion and subsequent response and reply, this case was transferred to this District for coordinated or consolidated pretrial proceedings pursuant to 28 U.S.C. § 1407. (Case No. 3:06-1166, Docket Entry 15, Exhibit 16). It appears that neither party objected to the transfer.

III. LEGAL DISCUSSION[5]

Only state actions that originally could have been filed in federal court may be removed to the federal court by

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[4] N.J.S.T. § 2A:58C-5 which states:

> Punitive damages shall not be awarded if a drug or device or food or food additive which cause the claimant's harm was subject to premarket approval or licensure by the federal Food and Drug Administration under the "Federal Food, Drug and Cosmetic Act," 52 Stat. 1040, 21 U.S.C. § 301 et seq. or the "Public Health Service Act," 58 Stat. 682, 42 U.S.C. § 201 et seq. and was approved or licensed; or is generally recognized as safe and effective pursuant to conditions established by the federal Food and Drug Administration and applicable regulations, including packaging and labeling regulations. However, where the product manufacturer knowingly withheld or misrepresented information required to be submitted under the agency's regulations, which information was material and relevant to the harm in question, punitive damages may be awarded.

[5] The Magistrate Judge stresses to both parties the well known concept that less is more. The superfluous citing of cases that only

the defendant. 28 U.S.C. § 1441. The party removing the case to federal court bears the burden of proving that the federal court has jurisdiction. *Id.* The question of whether a claim "arises under" federal law must be determined by reference to the "well-pleaded complaint" rule, examining the well pleaded allegations of the complaint and ignoring potential defenses. 28 U.S.C. §§ 1331, 1441; *Roddy v. Grand Trunk Western R.R. Inc.*, 395 F.3d 318, 322 (6th Cir.2005). The well-pleaded complaint rule recognizes that the plaintiff is the master of his complaint. *Id.* Accordingly, if the plaintiff chooses to bring a state law claim, that claim cannot generally be "recharacterized" as a federal claim for purposes of removal. *Id.* However, while this rule makes the plaintiff the master of his claim, the plaintiff may not avoid federal jurisdiction by omitting from the complaint allegations of federal law that are essential to the claim. If the plaintiff does so, a court may recharacterize the "artfully-pleaded" complaint as though it had been "well-pleaded."

One narrow exception to the well-pleaded complaint rule is the doctrine of "complete preemption."[6] This doctrine permits removal of an action to federal court when a federal statute wholly displaces a state law cause of action. *Strong v. Teletronics Pacing Sys., Inc.*, 78 F.3d 256 (6th Cir.1996).

Another relatively new, and equally limited, exception to the well-pleaded complaint rule is substantial federal

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marginally advance arguments is unnecessary as is the continuous repetition of the same arguments.

[6] The Supreme Court has demonstrated a reluctance to extend the application of the "complete preemption" exception. See *Palkow v. CSX Transp., Inc.*, 431 F.3d 543, 553-54 (2005), for a detailed account of when the Supreme Court has applied this very limited exception, mainly for those claims involving LMRA and ERISA as well as usury and copyright laws.

issue preemption. The Supreme Court has recently held that there is federal question jurisdiction, even in the absence of an express or implied federal cause of action, if a substantial federal question of great federal interest is raised by a complaint framed in terms of state law, and if resolution of that federal question is necessary to the resolution of that state-law claim. *Merrell Dow Pharmaceuticals, Inc., v. Thompson,* 478 U.S. 804, 106 S.Ct. 3229, 92 L.Ed.2d 650 (1986); *Grable & Sons Metal Products, Inc. v. Darue Engineering & Manufacturing,* 545 U.S. 308, 125 S.Ct. 2363, 162 L.Ed.2d 257 (2005).

A. Whether there is complete preemption

As the party invoking removal, and since the face of the Plaintiff's well-pleaded complaint does not state a federal claim, the Defendant bears the burden of establishing Plaintiffs' cause of action is completely preempted. Defendant asserted in it's Notice of Removal that this Court has jurisdiction under the doctrine of complete preemption because "Congress has so thoroughly and intentionally regulated the marketing and promotion of prescription medication that any challenge to such marketing and promotion necessarily states a federal cause of action: violation of the FDCA and its implementing regulations." (Case No. 3:06-1166, Docket Entry 15, Exhibit 3, ¶¶ 7, 8, and 9).[7] Plaintiffs responded in their Motion for Remand as well as in their reply brief that the complete preemption doctrine simply does not apply and that Defendant has cited no authority for this

[7] It should be noted that the Defendant did not advance it's complete preemption argument in it's Opposition to the instant Motion to Remand or during the January 22, 2007, hearing. However, given that it was originally one prong of Defendant's basis from removal, it is fully addressed in this Report and Recommendation.

assertion. (Case No. 3:06-1116, Docket Entry 15, Exhibit 14, Page 9-10, 12-13).

The Magistrate Judge agrees with the Plaintiffs. The Defendant confusingly blurs it's arguments regarding complete preemption which warrants removal with those of ordinary preemption of state law. Complete preemption that supports removal and ordinary preemption are two distinct concepts. *Roddy v. Grand Trunk Western R.R. Inc.*, 395 F.3d at 323 (citing 28 U.S.C. § 1441 and *Warner v. Ford Motor Co.*, 46 F.3d 531, 535 (6th Cir.1995)(en banc)). Complete preemption that permits removal is reserved for statutes designed to occupy the regulatory field with respect to a particular subject *and to create a superseding cause of action*, while ordinary preemption applies to statutory sections that arguably supersede conflicting state law. *Id.* (emphasis added). "In other words, the complete preemption doctrine is not simply one of preemption of the law, it is a sort of 'super' preemption which preempts not only the state law, but also creates federal jurisdiction-to use the jargon of the day, it is 'preemption on steroids.' " *Palkow v. CSX Transp., Inc.*, 431 F.3d 543, 553 (6th Cir.2005). Additionally, it is important to note that a case may not be removed to federal court on a the basis of a federal defense, including the defense of preemption, even if the defense is anticipated in the plaintiff's complaint, and even if both parties concede that the federal defense is the only question truly at issue. *Caterpillar Inc. v. Williams*, 482 U.S. 386, 107 S.Ct. 2425, 96 L.Ed.2d 318 (1987); *Baldwin v. Pirelli Armstrong Tire Corp.*, 927 F.Supp. 1046 (M.D.Tenn.1996).

It is now clear to the Magistrate Judge that the Defendant's arguments, while arguably supporting ordinary preemption of Plaintiffs' state law claims and/or federal question jurisdiction under substantial federal question

preemption as discussed in detail below, do not support a finding of complete preemption. "The congressional intent necessary to confer removal jurisdiction upon the federal district courts through complete preemption is expressed through creation of a parallel federal cause of action that would 'convert' a state cause of action into the federal action for purpose of the well-pleaded complaint rule." *Strong v. Teletronics Pacing Sys., Inc.*, 78 F.3d at 260; *Roddy v. Grand Trunk Western R.R. Inc.*, 395 F.3d 318 (6th Cir.2005). When Congress has indicated an intent to so completely occupy the field, any ostensibly state law claim is in fact a federal claim for purposes of arising-under jurisdiction. *Id.* Applying the standard to the instant matter, complete preemption does not apply as the FDCA does not create or imply a private right of action for individuals injured as a result of the violations of the Act.[8]

Given the limited number of statutes which the Supreme Court has found to "completely preempt" state law claims so as to permit recharacterization of a plaintiffs' claim as a federal claim so that removal is proper, as well as the Defendant's failure to cite to and the Mag-

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[8] Defendant has apparently made a similar arguments regarding misbranding and other labeling issues in previous litigation involving the use of the drug Elidel. *Perry v. Novartis Pharma. Corp.*, 456 F.Supp.2d 678 (E.D.Pa.2006). The Magistrate Judge notes that *Perry* was a diversity action and did not deal with the issue of remand. However, the FDCA conflict preemption analysis is still useful. Specifically, the Court found that, ". . . the bar to a finding of preemption is raised even higher because the FDCA provides no remedy for an injured consumer. Thus, a finding of preemption here will foreclose a remedy that was traditionally available and for which federal law provides no substitute. Courts have (understandably) been particularly reluctant to find preemption in such cases without an unambiguous signal of Congressional intent. Courts should therefore not reach to find that FDA regulations preempt state law claims." *Id.* at 684.

istrate Judge's inability to locate any cases which hold that labeling based claims under the FDCA are completely preempted, it is apparent that complete preemption should not be applied in the instant case. The fact that the Defendant might ultimately prove that Plaintiffs' claims are preempted under the FDCA does not establish that such state law based claims are now removable to federal court. See *Caterpillar,* 482 U.S. at 398.

B. Whether Plaintiffs' claims require the resolution of substantial federal issues

The Defendant also argues that federal question jurisdiction exists to support removal under the contours of 28 U.S.C. § 1331, as interpreted by recent Supreme Court holdings, which carve out a new, non-complete preemption form of federal question jurisdiction for purposes of removal of state law claims. *Palkow,* 431 F.3d at 554 (citing *Merrell Dow Pharmaceuticals, Inc. v. Thompson,* 478 U.S. 804, 106 S.Ct. 3229, 92 L.Ed.2d 650 (1986)). The Supreme Court now allows for federal jurisdiction if there is a substantial federal issue raised by a state action based complaint, if resolution of that federal issue is necessary to the resolution of that state-law claim. *Merrell Dow,* 478 U.S. at 804; see also *Grable & Sons Metal Products, Inc. v. Darue Engineering & Manufacturing,* 545 U.S. 308, 125 S.Ct. 2363, 162 L.Ed.2d 257 (2005).

The Defendant argues that there are two main substantial federal issues raised by the Plaintiffs' state action based complaint that warrant federal jurisdiction: (1) Plaintiffs' references in the Complaint in Count IV (Negligence-Failure to Warn) to the Defendant's alleged violation of the FDCA regarding warnings and labeling[9]

[9] The Defendant cites a laundry list of possible federal issues related to this issue. (Case No. 06-1166, Docket Entry 15, Exhibit 11, Pages 11-12).

and (2) the Plaintiffs' claims for punitive damages which Defendant argues requires the Plaintiffs to prove "fraud on the FDA" as a prerequisite to recovery. Plaintiffs respond that all causes of action are based solely upon state law and do not require that they prove the Defendant violated any portion of federal law as an element of, or prerequisite to, any of their claims. Plaintiffs further respond that even if federal issues are involved, such issues are not substantial to an extent that they warrant federal jurisdiction. Again, the Magistrate Judge agrees with the Plaintiffs that their state based action does not warrant federal jurisdiction.

1. Count IV (Negligence-Failure to Warn)

Similar to the instant case, the Supreme Court, in *Merrell Dow Pharmaceuticals, Inc. v. Thompson,* found that a state court negligence action against a drug manufacturer resting in part on the allegation that the defendant drug company had violated a federal misbranding prohibition did not present a federal question, so that removal of the action to federal court was improper. 478 U.S. 804, 106 S.Ct. 3229, 92 L.Ed.2d 650 (1986). The Supreme Court held that "a complaint alleging a violation of a federal statute as an element of a state cause of action, when Congress has determined that there should be no private, federal cause of action for the violation, does not state a claim 'arising under' " § 1331. *Id.* at 817. In short, Congress did not intend a private federal remedy for violations of the statute [the FDCA] that it enacted and therefore, the presence of a federal issue as an element of the state tort claim is not the kind of adjudication for which jurisdiction would serve congressional purposes and the federal system. *Id.* at 814. The Supreme Court found, even assuming that federal law would have to be applied to resolve the claim, that fed-

eral jurisdiction was unavailable after closely examining the strength of the federal issue at stake and the implications of opening the federal forum. *Id.* at 817.

The Supreme Court further clarified *Merrell Dow* in *Grable & Sons Metal Products, Inc. v. Darue Engineering & Manufacturing*, 545 U.S. 308, 125 S.Ct. 2363, 162 L.Ed.2d 257 (2005). The Court stated that *Merrell Dow* could not be read to make a federal cause of action created by Congress a necessary condition for federal question jurisdiction.[10] Specifically, the Court reiterated that *Merrell Dow* "should be read in its entirety as treating the absence of such cause as evidence relevant to, but not dispositive of, the 'sensitive judgements about congressional intent' required by § 1331." *Id.* at 309 (citing *Merrell Dow v. Thompson*, 478 U.S. at 810). The Court stated that while it could not state a "single, precise, all embracing" test for jurisdiction over federal issues embedded in state-law claims between non-diverse parties, the question to ask is:

> Does a state-law claim necessarily raise a stated federal issue, actually disputed and substantial, which a federal forum may entertain without disturbing any congressionally approved balance of federal and state judicial responsibilities?

The Court further detailed that in such cases, "federal jurisdiction demands not only a contested federal issue, but a substantial one, indicating a serious federal interest in claiming the advantages thought to be inherent in a federal forum." *Id.* at 313. Additionally, because aris-

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[10] There was an apparent split between the circuits on whether the holding in *Merrell Dow* meant there must always be a federal cause of action as a condition for exercising federal-question jurisdiction. The Supreme Court in *Grable*, as described above, resolved this issue.

ing-under jurisdiction always raises the possibility of upsetting the division of labor between the state and federal courts, even when the state action raises a contested and substantial federal issue, this issue will only qualify for federal jurisdiction if it is "consistent with congressional judgment" on the proper division of labor between the two court systems. *Id.* The Court concluded stating that Merrell Dow's "analysis thus fits within the framework of examining the importance of having a federal forum for the issue, and the consistency of such a forum with Congress's intended division of labor between state and federal courts." *Id.* at 319.

In *Merrell Dow,* the Court held that a general rule of exercising federal jurisdiction over state claims resting on federal mislabeling and other statutory violations would have "heralded a potentially enormous shift of traditionally state cases into federal courts." *Grable v. Darue,* 545 U.S. at 319 (citing *Merrell Dow v. Thompson,* at 811-812). In *Grable,* the Court upheld this portion of it's decision in *Merrell Dow* stating: "For if the federal labeling standard without a federal cause of action could get a state claim into federal court, so could any other federal standard without a federal cause of action. And that would have meant a tremendous number of cases." *Id.* at 318.

The standards set by both *Merrell Dow* and *Grable* purposefully do not set clear jurisdictional boundaries. Rather, the Supreme Court has made it clear that each case involving an alleged violation of the FDCA must be reviewed to determine whether it should be distinguished on its facts from those in *Grable* and *Merrell Dow.* In the instant case, given the significance of the assumed Congressional preclusion of federal private remedies for misbranding under the FDCA as well as the "potentially enormous shift of traditionally state cases into federal courts," the Magistrate Judge finds any pos-

sible federal issues related to Plaintiffs' failure to warn claims, as alleged and described by both the Plaintiffs and the Defendant, do not rise to the kind of adjudication for which federal jurisdiction would serve congressional purposes and the federal system. *Grable v. Darue*, 545 U.S. at 319 (citing *Merrell Dow v. Thompson*, at 811-812). While the Magistrate Judge has reviewed the Defendant's list of *potential* federal issues,[11] given the Supreme Court's holdings in *Grable* and *Merrell Dow*, these are not substantial to the extent that the Plaintiffs' case rests on the resolution of these issues. In spite of Defendant's blanket assertions to the contrary, Plaintiffs' stated causes of action do not require proof of violation of federal law as an essential element to recovery.[12] *Grable v. Darue*, 478 U.S. at 814. The Magistrate Judge believes these issues, if they arise, could be properly handled by the state court as part of Plaintiffs' state law claims.[13]

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[11] Case No. 3:06-cv-01166 Docket Entry 15, Exhibit 11, Pages 11-12.

[12] It should also be noted that the Plaintiffs are not requesting that the Defendant modify it's label and related packaging in violation of FDA regulations nor are the Plaintiffs suing the FDA itself in this action.

[13] Interestingly, Defendant has made similar preemptive arguments when requesting a motion to dismiss, again in *Perry v. Novartis Pharmaceuticals Corp.*, 456 F.Supp.2d 678 (E.D.Pa.2006). The Court rejected Defendant's preemption arguments stating that:

> If at some future date, Congress determines that FDA monitoring is sufficiently effective on its own to warrant the elimination of state law incentives for manufacturers to provide adequate warnings, it also has the authority to declare that failure to warn suits, like the Perry's action, are preempted. Until it does so, however, in the absence of a specific FDA safety determination, such suits can go forward. *Perry*, 456 F.Supp. at 687.

Further, the Defendant argues at length that the novelty of these issues, especially in light of the recent FDA preamble,[14] justifies the retention of Plaintiffs' labeling based claims. However, in *Merrell Dow*, the Supreme Court clearly stated that:

> We do not believe the question whether a particular claim arises under federal law depends on the novelty of the federal issue. Although it is true that federal jurisdiction cannot be based on a frivolous or insubstantial federal question, 'the interrelation of federal and state authority and the proper management of the federal judicial system,' would be ill served by a rule that made the existence of federal-question jurisdiction depend on the district court's case-by-case appraisal of the novelty of the federal question asserted as an element of the state tort. The novelty of an FDCA issue is not sufficient to give it status as a federal cause of action; nor should it be sufficient to give a state-based FDCA claim status as a jurisdiction-triggering federal question. 478 U.S. at 817 (citing *Franchise Tax Board v. Construction Laborers Vacation Trust*, 463 U.S. 1, 8, 103 S.Ct. 2841, 77 L.Ed.2d 420 (1983).

Therefore, the novelty of any possible federal issues presented by the Defendant is clearly not sufficient to establish federal question jurisdiction.

2. Plaintiffs' claims for punitive damages

A more interesting argument is made by the Defendant related to Plaintiffs' punitive damages claims. However,

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[14] The *Perry* Court, in response to Defendant's reliance on the non-binding authority of the recent FDA preamble which arguably takes the position that its labeling requirements should have a pre-

while the Magistrate Judge agrees with the Defendant that state courts cannot step into the shoes of the FDA to determine whether a fraud on the FDA has been committed, Plaintiffs' claims for punitive damages still do not warrant federal jurisdiction, for reasons discussed in detail below.

The relevant portion of N.J. Stat. Ann. § 2A:58C-5(c) states: ". . . where the product manufacturer knowingly withheld or misrepresented information required to be submitted under the agency's regulations, which information was material and relevant to the harm in question, punitive damages may be awarded."[15]

The Defendant makes the argument that Plaintiffs' claim for punitive damages raises a substantial federal question because New Jersey's punitive damages statute incorporates federal law by providing for a "fraud on the FDA" exception. The Defendant contends that the Plaintiffs are barred from recovering punitive damage unless the Plaintiffs establish the Defendant "knowingly withheld or misrepresented" material and relevant information to the FDA, which would require Plaintiffs to establish that the Defendant violated federal law in its submission of materials to the FDA.

Plaintiffs respond that their claims do not turn on a "fraud on the FDA claim," but rather that New Jersey law sets a standard where a plaintiff need only show that

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emptive effect (71 Fed.Reg. 3922 (Jan. 24, 2006)), persuasively stated that Congress, not federal agencies, have the power to preempt state law claims as "Agencies may play the sorcerer's apprentice but not the sorcerer himself." *Perry*, at 683 (quoting *Alexander v. Sandoval*, 532 U.S. 275, 291, 121 S.Ct. 1511, 149 L.Ed.2d 517 (2001). The Magistrate Judge agrees with the *Perry* Court's analysis on the deference to the FDA's preamble and advisory opinions and therefore, need not repeat it here at length. See *Perry*, 456 F.Supp. at 682-84.

[15] For the statute's full text, see footnote 4. 14

the drug company withheld information that was material and relevant to the harm in question in order to support a punitive damages claim. Plaintiffs assert that no inquiry into FDA procedures or analysis or speculation as to what the FDA would have done with the information is necessary.

The Supreme Court has expressly considered the question of a state common law fraud-on-the-FDA tort claim and has found that it is impliedly preempted by the FDCA. *Buckman Company v. Plaintiffs' Legal Committee,* 531 U.S. 341, 121 S.Ct. 1012, 148 L.Ed.2d 854 (2001). *Buckman* was a diversity case where the plaintiffs' theory of liability was that but-for the defendant's fraudulent statements to the FDA, the bone screws would have never received FDA approval, and the plaintiffs would not have been injured. 531 U.S. 341, 121 S.Ct. 1012, 148 L.Ed.2d 854 (2001). The Supreme Court found that, "Policing fraud against federal agencies is hardly 'a field which the States have traditionally occupied.' " *Id.* at 347 (citing *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 67 S.Ct. 1146, 91 L.Ed. 1447 (1947)). Further, the Supreme Court found that state law fraud-on-the-FDA claims inevitably conflict with the FDA's responsibility to police fraud consistently with the Agency's judgement and objectives. *Id.* at 350. The Supreme Court was concerned that "complying with the FDA's detailed regulatory regime in the shadow of 50 States' tort regimes will dramatically increase the burdens facing potential applicants-burdens not contemplated by Congress in enacting the FDCA . . ." *Id.* Further, fraudon-the-FDA claims "would also cause applicants to fear that their disclosures to the FDA, although deemed appropriate by the Administration, will later be judged insufficient in state court. Applicants would then have an incentive to submit a deluge of

information that the Administration neither wants or needs, resulting in additional burdens on the FDA's evaluation of an application" causing delays and impeding competition. *Id.* at 351.

In contrast to *Buckman*, the present case does not involve a claim of fraud-on-the-FDA but instead involves a state statute which immunizes drug manufacturers from punitive damage liability *unless* the plaintiff can prove fraud on the FDA. Stated differently, *Buckman* involved a specific cause of action for fraud on the FDA, whereas the instant Plaintiffs must prove fraud on the FDA merely as a prerequisite to obtaining punitive damages under New Jersey law.

It appears that two other courts have considered this very same issue. In *Garcia v. Wyeth-Ayerst*, a diversity action, the plaintiff brought a products liability action against a drug manufacturer seeking punitive damages. 385 F.3d 961 (2004). Michigan, like New Jersey, immunizes drug manufacturers from punitive damage liability in actions based on injuries from FDA-approved drugs absent a showing that the drug manufacturers secured FDA approval through fraud. The Sixth Circuit held that the distinction between a plaintiff who brought a direct cause of action for fraud on the FDA and a plaintiff who had to prove fraud on the FDA merely as a prerequisite to obtaining punitive damages under Michigan law was immaterial in light of *Buckman*. *Id.* at 965-66. The Sixth Circuit held that regardless of whether a plaintiff is required to prove fraud on the FDA as a cause of action unto itself or simply as a prerequisite in a punitive damages action, "such a state court proceeding would raise the same inter-branch-meddling concerns that animated *Buckman*." *Id.* at 966 (citing *Buckman*, 531 U.S. at 351).

The Sixth Circuit did find that the Michigan law fraud exceptions, under *Buckman*, could be applied in certain

situations. "Doubtless, *Buckman* prohibits a plaintiff from invoking the exceptions on the basis of a *state court* findings of fraud on the FDA . . . . [however those concerns stated in *Buckman]* do not arise when the *FDA itself* determines that a fraud has been committed on the agency during the regulatory-approval process." *Id.* at 966. "Thus, in this setting, it makes abundant sense to allow a State that chooses to incorporate a federal standard into the law of torts to allow that standard to apply when the federal agency itself determines that fraud marred the regulatory-approval process. In the final analysis, the exemptions are invalid as applied in some settings (e.g, when a plaintiff asks a state court to find bribery or fraud on the FDA) but not in others (e.g. claims based on federal findings of bribery or fraud on the FDA)." *Id.* Therefore, the Sixth Circuit found that the Michigan law did not conflict with the FDCA as long as the proof of the fraud-on-the-FDA element was satisfied only by a finding by the FDA itself that it had been defrauded. *Id.* at 966.[16] The Sixth Circuit concluded that absent such a finding by the FDA, the statute was unconstitutional but severable, placing "responsibility for prosecuting bribery or fraud on the FDA in the hands of the Federal Government rather than state courts." *Id.* at 967.

In *Kobar v. Novartis Corporation,* the same issue was presented as in *Garcia,* in the context of a similar Arizona statute, on a motion for partial summary judgment on the issue of punitive damages. 378 F.Supp.2d 1166 (2005). There, the Plaintiff made the same argument as the Plaintiffs in the instant case, i.e. that she did not

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[16] This is supported in *Buckman* by Justice Stevens, concurring: "If the FDA determines both that fraud has occurred and that such fraud requires the removal of products from the market, state damage remedies would not encroach upon, but rather would supplement and facilitate, the federal enforcement scheme." 531 U.S. at 354.

have to prove fraud on the FDA but rather merely that the drug manufacturer withheld "material and relevant" information from the FDA during the approval process. *Id.* at 1172-73. However, the *Kobar* Court was not persuaded by the distinction finding that: "Both common law fraud on the FDA claim and an immunity statute that requires a plaintiff to prove fraud on the FDA in order to collect punitive damages place state courts, as finders of fact, in the uncomfortable and difficult position of having to answer the question of what role, if any, the allegedly withheld information would have played in the FDA's complicated approval process." *Id.* The *Kobar* Court further stated that the "FDA is equally empowered to police and deter fraud with respect to the drug approval process . . . [and] the FDA has the authority to request additional information from a drug manufacturer, investigate suspected fraud, seek injunctive relief and civil penalties and pursue criminal prosecutions." *Id.* at 1173. As in *Garcia*, the *Kobar* Court found that severing the fraud exceptions from the rest of the Arizona statute would still allow a plaintiff to obtain punitive damages so long as the FDA itself made a finding that it has been defrauded by the drug manufacturer. *Id.* at 1176. Also as in *Garcia*, the *Kobar* Court found that the statute was unconstitutional in all situations except when the FDA makes a finding that it has been defrauded. *Id.* at 1174-75.[17]

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[17] The Second Circuit, interpreting the same Michigan law, has disagreed with the Sixth Circuit's holding in *Garcia*. In *Desiano v. Warner-Lambert & Co.*, the Second Circuit found that federal law did not preempt the punitive damages immunity exception. 467 F.3d 85 (2nd Cir.2006). The Second Circuit advanced that the immunity granted by the Michigan statute was in the form of an affirmative defense for drug manufacturers regarding punitive damage liability and that,

> "Finding preemption of traditional common law claims where fraud is not even a required element-but may be submitted to neutralize a drugmaker's use of an affir-

Neither *Buckman, Garcia* or *Kobar* address whether the request for punitive damages when there is a fraud-on-the-FDA exception is a substantial issue which warrants removal to federal court. Therefore, this is a novel issue presented to this Court. At this point, the Magistrate Judge goes back to the standard set by the Supreme Court in *Grable:*

> Does a state-law claim necessarily raise a stated federal issue, actually disputed and substantial, which a federal forum may entertain without disturbing any congressionally approved balance of federal and state judicial responsibilities? 545 U.S. at 313.

Further, it is important to again note that a case may not be removed to federal court on a the basis of a federal defense, including the defense of preemption, even if the defense is anticipated in the plaintiff's complaint, and even if both parties concede that the federal defense is the only question truly at issue. *Caterpillar Inc. v.*

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mative defense available under state law-would result in preemption of a scope that would go far beyond anything that has been applied in the past. Until and unless Congress states explicitly that it intends invalidation of state common law claims merely because issues of fraud may arise in the trial of such claims, we decline to read general statutes like the FDCA and the MDA as having that effect." *Id.* at 96.

The Magistrate Judge respectfully disagrees with the Second Circuit's interpretation of the Michigan statute which provides drug manufacturer's, not with an affirmative defense, but with absolutely immunity regarding punitive damages absent a showing that the drug manufacturer secured FDA approval through fraud. For the reasons clearly outlined above, the Magistrate Judge believes that the FDA itself must make this finding of fraud.

Williams, 482 U.S. 386, 107 S.Ct. 2425, 96 L.Ed.2d 318 (1987). *Baldwin v. Pirelli Armstrong Tire Corp.*, 927 F.Supp. 1046 (M.D.Tenn.1996).

Because of its important role in state regulation of matters of health and safety, common law liability cannot be easily displaced in our federal system. The object of the New Jersey legislature in creating this statute was to regulate and restrict when Plaintiffs could recover punitive damages, which falls squarely within its prerogative to regulate matters of health and safety. Where Plaintiffs seek punitive damages under the New Jersey statute in either state or federal courts and the issue on fraud-on-the-FDA is raised, the potential would exist for the FDA's personnel to be drawn into those controversy on a case-by-case basis over and over again. This would generate a wholly impractical situation. Therefore, the Magistrate Judge believes that, in the instant case, the Plaintiffs, whether in federal or state court, will not be entitled to punitive damages absent a finding *by the FDA* that the Defendant committed fraud on the agency. The concerns expressed in *Buckman*, *Garcia* and *Kobar*, such as state courts having to step into the shoes of the FDA in making fraud determinations and the possible delay in the drug approval if applicants feared that their disclosures to the FDA although deemed appropriate by the Administration will later be judged insufficient in state courts, are also equally true if federal courts, on a federal district by federal district or even federal circuit by federal circuit, make determinations of fraud. As such, whether in federal or state court, the FDA will need to make a finding on the matter of fraud before the Plaintiffs will be entitled to recover punitive damages under New Jersey law.

With all of this said, it is the Magistrate Judge's belief that Plaintiffs' claims for punitive damages will not

require the New Jersey state court to find fraud-on-the-FDA and as such, no substantial federal issue is present which warrants federal jurisdiction. Rather, the Defendant will have to present a defense to the New Jersey state court, similar to the Defendants in *Garcia* and *Kobar*, that the portion of the New Jersey statute which requires Plaintiffs to demonstrate that "the product manufacturer knowingly withheld or misrepresented information required to be submitted under the agency's regulations, which information was material and relevant to the harm in question" is preempted and can only be satisfied by an FDA finding of fraud. As noted above, this federal preemption defense is not sufficient to remove a state law complaint to federal court.

In summary, the Magistrate Judge believes that the Plaintiffs will be required to submit a finding by the FDA of fraud prior to being able to recover punitive damages in either state court or in federal court. While this specific issue preemption argument has not been presented in regards to the New Jersey statute in question, the Defendant can present such an argument as a defense in state court if needed. As such, there is no substantial issue presented regarding punitive damages which warrants federal jurisdiction.

C. Whether Plaintiffs are entitled to attorneys' fees

The Magistrate Judge believes that the Defendant had an objectively reasonable basis for seeking removal, when considering the combined effect of all of it's arguments regarding labeling as well as it's novel argument regarding punitive damages. Therefore, the Plaintiffs are not entitled to their attorneys' fees and costs incurred as a result of the removal. 28 U.S.C. § 1447(c).

IV. RECOMMENDATION

For the reasons stated above, the Magistrate Judge recommends that the Plaintiffs' Consolidated Motion for Remand be **GRANTED** and that Plaintiffs' causes of action be **REMANDED** to New Jersey state court. Further, the Magistrate Judge recommends that Plaintiffs' request for attorneys' fees be **DENIED.**

Under Rule 72(b) of the Federal Rules of Civil Procedure, any party has ten (10) days from receipt of this Report and Recommendation in which to file any written objections to this Recommendation, with the District Court. Any party opposing said objections shall have ten (10) days from receipt of any objections filed in this Report in which to file any responses to said objections. Failure to file specific objections within ten (10) days of receipt of this Report and Recommendation can constitute a waiver of further appeal of this Recommendation. *Thomas v. Arn,* 474 U.S. 140, 106 S.Ct. 466, 88 L.Ed.2d 435 (1985), *reh'g denied,* 474 U.S. 1111, 106 S.Ct. 899, 88 L.Ed.2d 933 (1986).

UNITED STATES DISTRICT COURT
D. MINNESOTA

No. MDL 01-1396 JRTFLN
Jan. 5, 2004

In re: ST. JUDE MEDICAL, INC. SILZONE HEART VALVES PRODUCTS LIABILITY LITIGATION

J. Gordon Rudd, Jr. and Charles S. Zimmerman, Zimmerman Reed, P.L . L.P., Minneapolis, MN, Steven E. Angstreich, Michael Coren, and Carolyn Lindheim, Levy, Angstreich, Finney, Baldante, Rubenstein & Coren, P.C., Woodcrest Pavilion, Cherry Hill, NJ, James T. Capretz, Capretz & Assoc., Newport Beach, CA, Joe D. Jacobson, Green, Schaaf & Jacobson, P.C., St. Louis, MO, and Patrick Murphy, Bochanis and Murphy Legal Associates, Las Vegas, NV, for plaintiffs.

Tracy J. Van Steenburgh, Halleland, Lewis, Nilan, Sipkins & Johnson, Minneapolis, MN, James C. Martin and David E. Stanley, Reed Smith Crosby Heafey LLP, Los Angeles, CA, Steven M. Kohn, Reed Smith Crosby Heafey LLP, Oakland, CA, for defendant.

MEMORANDUM OPINION AND ORDER DENYING DEFENDANT'S MOTION FOR SUMMARY JUDGMENT

TUNHEIM, J.

On April 18, 2001, the cases making up this multidistrict litigation were transferred to this Court by the Judicial Panel on Multidistrict Litigation for consolidated pretrial proceedings under 28 U.S.C. § 1407. Defendant St. Jude Medical ("St. Jude" or "SJM") requests summary judgment, arguing that all plaintiffs' claims are preempted by federal law. Plaintiffs argue that key material fact questions prevent summary judgment. The motion was extensively briefed, and the Court heard lengthy argument on the matter. For the reasons discussed below, defendant's motion is denied.

BACKGROUND

I. Factual Background[1]

Defendant St. Jude, a company with headquarters and manufacturing facilities in Minnesota, manufactures a variety of medical devices including prosthetic heart valves. Such valves are surgically implanted into patients whose natural valves have been damaged by disease. Among St. Jude's products is the Silzone heart valve, which has a coating of silver on the sewing cuff,

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[1] In support of their respective positions, both parties submitted multi-volume Appendices. For ease of reference, the Court will cite to these Appendices as, for example, "Pl.App. Vol. *X* at Tab. *Y*." In addition, defendant submitted two affidavits not in Appendix form. Those will be referred to by the last name of the affiant, and the Tab (exhibit) number. Finally, the Court also cites to the parties' respective memoranda as "Def. Brief" or "Def. Reply" and "Pl. Brief."

the part of the valve that is sewn to the patient's body. Aside from the silver coating, the Silzone valve is essentially the same as other St. Jude heart valves that have been approved by the U.S. Food and Drug Administration ("FDA") since 1995. Silver has been known to have anti-microbial properties, and St. Jude introduced the silver-coated valves to combat endocarditis, a potentially life-threatening infection of the cardiac tissue that is a well-known possible consequence of prosthetic heart valve implantation.

The FDA approved the Silzone valve for commercial distribution on March 24, 1998. As part of this approval, however, the FDA prohibited St. Jude from claiming that the Silzone coating would reduce the risk of endocarditis, as no clinical tests had been performed to study this claim.[2] After the FDA approved the Silzone valve, St. Jude sponsored the Artificial Valve Endocarditis Reduction Trial ("AVERT") study, a multinational clinical trial designed to study whether the Silzone-coated heart valve reduced the incidence of endocarditis in humans. Approximately 36,000 Silzone valves have been implanted in patients worldwide, with approximately 10,535 of these in the United States. AVERT was originally intended to involve 4,400 heart valve patients. However, the study enrolled only 792 patients, with approximately half of those receiving Silzone-coated valves and another half, the control group, receiving conventional (non-Silzone) valves. The results of AVERT are reviewed by an independent monitoring board.

In January 2000, the AVERT monitoring board reported that recipients of the Silzone valve were more

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[2] The FDA also required that all labels bearing the name "Silzone" must carry the following statement: "No clinical studies have been performed to evaluate the effect of the Silzone coating in reducing the incidence of endocarditis."

likely than recipients of conventional valves to experience a complication called paravalvular leak,[3] requiring the prosthetic valve to be removed and replaced with another valve. The data showed that two percent of AVERT participants with Silzone valves required such an "explant," while only .25 percent of participants with conventional valves required the procedure. On January 21, 2000, the monitoring board decided to suspend enrollment in the AVERT trial because of this increase in paravalvular leak.[4] On the same day, St. Jude voluntarily recalled all un-implanted Silzone products. As part of the recall, St. Jude notified hospitals and physicians, instructing them not to use Silzone products. St. Jude also sent letters regarding the care and management of patients with implanted Silzone valves, and established a reimbursement program to pay for uninsured medical costs associated with the detection, diagnosis and treatment of paravalvular leak.

In response to the voluntary recall, the FDA informed St. Jude that its actions would be considered a "recall." *See* Plaintiffs' Appendix Vol. VI, Ex. 100, March 20, 2000, Memorandum from Cardiovascular and Neurological Devices Branch ("We are assigning recall numbers to [Silzone valves] . . . We are classifying the firm's actions as a voluntary recall."). *See also* Plaintiffs' Appendix Vol. V, Ex. 24, March 22, 2000 letter from Edwin Dee to St. Jude ("We agree with your firm's decision to recall [the Silzone valve] . . . We have reviewed your action and conclude that it meets the for-

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[3] Paravalvular leak involves leakage at the point where a heart valve is sutured to a patient's tissue. *See* J.E. Schmidt, *Attorney's Dictionary of Medicine and Word Finder,* Vol. 4, P-79 (2002).

[4] Although enrollment in AVERT was suspended, the participants continue to be monitored and data are still collected and studied.

mal definition of a 'Recall'. This is significant, as your action is an alternative to a Food and Drug Administration legal action to remove the defective products from the market.").

II. Statutory Regulatory Scheme

Regulation of medical devices is governed by the Federal Food, Drug, and Cosmetic Act (FDCA), 52 Stat. 1040, as amended by the Medical Device Amendments of 1976(MDA), 90 Stat. 539, 21 U.S.C. § 301. *See generally Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 344 (2001). Devices are separated into three Classes (I, II, and III). The Silzone valve is a Class III device. Class III devices are defined as those devices that "presen[t] a potential unreasonable risk of illness or injury." § 360c(a)(c)(ii)(II). Because of the potential risks, Class III devices are subject to the strictest regulation of the three classes of devices. *Id.*

Typically, Class III devices must undergo an exhaustive review process with the FDA, called premarket approval (PMA) before they may be approved and marketed. The PMA "requires the applicant to demonstrate a 'reasonable assurance' that the device is both 'safe . . . [and] effective under the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof.' " *Buckman*, 531 U.S. at 344 (quoting §§ 360e(d)(2)(A), (B)).

There are also "exemptions" to the PMA process, one such exemption is the 510k exemption. The 510k process allows devices that are "substantially equivalent" to medical devices in existence in 1976 to be marketed and sold without PMA approval, in order not to stifle competition with technology existing at the time of the enactment of the MDA. See 21 U.S.C. § 360j(g)(1). This limited form of review "averages only 20 hours of

review as opposed to some 1200 hours in the PMA process." *Kemp v. Medtronic, Inc.*, 231 F.3d 216, 221-22 (6th Cir.2000) (herinafter "*Kemp*") (citing *Martin v. Telectronics Pacing Sys.*, 105 F.3d 1090, 1095 (6th Cir.1997); *Reeves v. AcroMed Corp.*, 103 F.3d 442, 446 (5th Cir.1997)).[5]

If the FDA approves a PMA, "it does so subject to conditions described in a document entitled 'Conditions of Approval.' " *Kemp*, 231 F.3d at 223. The Conditions of Approval form "requires manufacturers to submit the device's proposed labeling before marketing, limits advertising to the approved labeling, requires the manufacturer to submit a PMA supplement for review and approval before making any change affecting the safety or effectiveness of the device, requires the manufacturer to submit post-approval reports, and requires the manufacturer to report any incidents of adverse reaction to, or known defect of, the approved device." *Woods v. Gliatech, Inc.*, 218 F.Supp.2d 802, 805-06 (W.D.Va.2002).

FDA regulations provide that:

> FDA may impose postapproval requirements in a PMA approval order . . . Postapproval requirements may include as a condition to approval of the device: . . . (2) continuing evaluation and periodic reporting on the safety, effectiveness, and reliability of the device for its intended use. FDA will state in the PMA approval order the reason or purpose for

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[5] There is also an exemption for experimental or investigational devices (investigational device exemption or "IDE"). The IDE provides an exemption for devices representing innovative technology, and allows for unapproved devices to be utilized in human trials. An IDE permits a manufacturer to market "a device that otherwise would be required to comply with a performance standard or to have premarket approval for the purpose of conducting investigations of that device." 21 C.F.R. § 812.1.

> such requirement and the number of patients to be evaluated and the reports required to be submitted . . . (9) Such other requirements as FDA determines are necessary to provide reasonable assurance, or continued reasonable assurance, of the safety and effectiveness of the device.

21 C.F.R. § 814.82(a). "A device may not be manufactured, packaged, stored, labeled, distributed, or advertised in a manner that is inconsistent with any conditions to approval specified in the PMA approval order for the device." 21 C.F.R. § 814.80.

The FDA can withdraw approval if the manufacturer has not met all post-approval requirements, if the device is unsafe or ineffective, or if the PMA contained or was accompanied by an untrue statement of material fact. 21 U.S.C. § 360(e)(1) and 21 C.F.R. 814.46. At least one court has held that the failure to comply with PMA conditions invalidates FDA approval. *Woods*, 218 F.Supp.2d at 808 n.4.

III. Approval of the Silzone Valve

The Silzone valve was a modification to St. Jude's previously approved heart valve, as such, the Silzone valve itself did not go through the PMA process, but instead was approved via the "PMA Supplement" process.[6] 21 U.S.C. § 360e(d)(6)(A)(i); 21 C.F.R. § 814.39. *See Kemp v. Medtronic, Inc.*, 231 F.3d 216, 221-22 (6th Cir.2000) ("Should a manufacturer merely propose to modify a Class III device that has already received approval pursuant to the PMA process, the manufacturer may submit a PMA Supplement rather than re-submit-

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[6] The previously approved valve was the "Masters Series" valve, which itself was approved via a PMA supplement, rather than the full-blown PMA process.

ting the entire device for review.") *See generally United States v. Prigmore*, 243 F.3d 1, 5 (1st Cir.2001) (describing PMA supplement process). The PMA Supplement, like the initial PMA application "must contain scientific information that provides a basis for approval of the modified device." *Prigmore*, 243 F.3d at 5 (quoting 21 C.F.R. § 814.39(c)). *Id.* "All procedures and actions that apply to [a PMA] application under § 814.20 also apply to PMA supplements." § 814.39(c).

Defendant argues that approval pursuant to a PMA supplement is "sufficient evidence" that the device is "reasonably safe and effective for its intended use," and that therefore any claims based on the safety or efficacy of the device must be preempted. (Def. Brief at 17.) Defendant has submitted volumes of exhibits in support of its argument that the FDA carefully considered the approval, and that the PMA Supplement was exhaustive. For example, defendant submits exhibits indicating that St. Jude provided at least five "addendums" to the PMA Supplement. Each supplement addressed specific concerns voiced by FDA officials or consultants.

Despite this evidence, plaintiffs assert that FDA approval was improperly secured and unlawfully maintained. In support of this argument, plaintiffs submit the affidavits of three experts.[7] The gist of those affidavits is that St. Jude concealed information from the FDA, and that had that information been made available, the FDA would not have approved the valve. Plaintiffs suggest that because their claims are premised on the contention that St. Jude failed to comply with FDA regulations, there is no preemption. *See Brooks*, 273 F.3d at 798 ("a claim of failure to comply with FDA regulations is not preempted by the MDA, since such a state

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[7] These affidavits are the subject of a motion to strike, which is addressed below.

claim imposes no requirements different from, or in addition to any federal requirement") (internal quotation and citations omitted).

Plaintiffs also argue that although the approval was ostensibly PMA approval, in reality the FDA used a 510k-type approval (the much less intensive approval described above). The 510k process was at issue in *Medtronic, Inc. v. Lohr,* 518 U.S. 470 (1996) (herinafter "*Lohr*") a case in which the Supreme Court determined that plaintiff's claims were not preempted. Citing *Lohr,* plaintiffs argue that because 510k approval is based on equivalence, not safety, their claims are not preempted. Finally, plaintiffs alternatively argue that the express preemption of 360k(a) cannot apply, because the device approved is actually a drug or drug/device combination, not a device. The distinction between drug and device, plaintiffs argue, is one for the Court. Plaintiffs suggest that the FDA never determined that the Silzone valve was a device, rather than a drug/device combination. Even if the FDA made such a determination, plaintiffs continue, this Court owes no deference to it because Congress, and not the FDA, divided medical implements into categories of either drug or device.

ANALYSIS

I. Standard of Review

Rule 56(c) of the Federal Rules of Civil Procedure provides that summary judgment "shall be rendered forthwith if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." Fed.R.Civ.P. 56. Only

disputes over facts that might affect the outcome of the suit under the governing substantive law will properly preclude the entry of summary judgment. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). Summary judgment is not appropriate if the dispute about a material fact is genuine, that is, if the evidence is such that a reasonable jury could return a verdict for the nonmoving party. *Id.* Summary judgment is to be granted only where the evidence is such that no reasonable jury could return a verdict for the nonmoving party. *Id.*

The moving party bears the burden of bringing forward sufficient evidence to establish that there are no genuine issues of material fact and that the movant is entitled to judgment as a matter of law. *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986). The nonmoving party is entitled to the benefit of all reasonable inferences to be drawn from the underlying facts in the record. *Vette Co. v. Aetna Casualty & Surety Co.*, 612 F.2d 1076, 1077 (8th Cir.1980). However, the nonmoving party may not merely rest upon allegations or denials in its pleadings, but it must set forth specific facts by affidavits or otherwise showing that there is a genuine issue for trial. *Forrest v. Kraft Foods, Inc.*, 285 F.3d 688, 691 (8th Cir.2002).

II. Preemption Principles

The Supremacy Clause of the United States Constitution provides that the "Laws of the United States . . . shall be the supreme Law of the Land." U.S. Const. art. VI, cl. 2. The principle of preemption is the application of this clause, resulting in the rule that any "state law that conflicts with federal law is 'without effect.' " *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 516 (1992). Preemption is disfavored in areas of historic importance to the states' police powers-areas such as

public health and safety. *Kemp v. Medtronic, Inc.*, 231 F.3d 216, 222 (6th Cir.2000). *See also Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001) (no presumption against preemption where plaintiffs' claims involved medical devices, but were more accurately characterized as "fraud on the FDA" claims because "[p]olicing fraud against federal agencies is hardly a field which the States have traditionally occupied") (internal quotation omitted).

Preemption is typically understood as having two types-express and implied. Express preemption is found when Congress "pre-empt[s] state law by so stating in express terms." *Hillsborough County, Fla. v. Automated Med. Labs, Inc.*, 471 U.S. 707, 712-13 (1985) (citing *Jones v. Rath Packing Co.*, 430 U.S. 519, 525). Implied preemption, in turn, has two types-field preemption, and conflict preemption. Field preemption occurs when Congress legislates so pervasively in a particular field that no room remains for concurrent state legislation. *Id.* Conflict preemption occurs

> [e]ven where Congress has not completely displaced state regulation in a specific area, state law is nullified to the extent that it actually conflicts with federal law. Such a conflict arises when compliance with both federal and state regulations is a physical impossibility, or when state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.

Id. (internal quotations omitted).

"Central to determining questions of preemption is divining Congress' intent." *Kemp v. Medtronic, Inc.*, 231 F.3d 216, 222 (6th Cir.2000) (citing *Cipollone*, 505 U.S. at 517-18). Courts must be careful to avoid the "unintended encroachment on the authority of the States" and

therefore "will be reluctant to find pre-emption" where the subject is one "traditionally governed by state law." *CSX Transp., Inc. v. Easterwood*, 507 U.S. 658, 663-64 (1993). Where Congress has included an express pre-emption provision in a statute, courts historically have not looked beyond it to consider implied preemption. *Kemp*, 231 F.3d at 222. However, since *Buckman Co. v. Plaintiff's Legal Comm.*, it is clear that express and implied preemption are not mutually exclusive. Therefore, the Court discusses both express and implied pre-emption.

A. Express Preemption-Section 360k

At issue in these cases is the express preemption provision of the MDA, which states:

> [N]o State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—(1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. § 360k(a) (emphasis added).

1. What is a "requirement"

Courts have struggled to divine Congress's intent in § 360k-specifically, courts have differed in the understanding of what was meant by the term "requirement" in the context of a "requirement" imposed by a State (or political subdivision). Some courts have reasoned that "requirement" is intended to encompass only State legislative, statutory "requirements." *See Oja v. Howemed-*

ica, Inc., 111 F.3d 782, 789 (10th Cir.1997) (interpreting *Lohr* and holding that "requirement" meant only state statutory requirements). Others determined that the term "requirements" was intended to include common-law tort claims as well. *See, e.g., Martin*, 254 F.3d at 579-83; *Kemp*, 213 F.3d at 224.

These differing understandings stem from the Supreme Court's discussion of "requirements" in *Lohr*. Justice Stevens, writing for a plurality, rejected as "implausible" the medical device manufacturer's suggestion that "any common-law cause of action is a 'requirement' which alters incentives or imposes duties 'different from, or in addition to,' the generic federal standards." *Lohr*, 518 U.S. at 486-87. Justice Stevens discussed the language of § 360k, the legislative history, and the fact that members of both houses "were acutely aware of ongoing product liability litigation" when the section was enacted. *Id.* at 487-491. Stevens concluded that § 360k "simply was not intended to pre-empt most, let alone all general common-law duties enforced by damages actions." *Id.* at 491. Despite this discussion, Stevens did not "respond directly" to the plaintiff's contention that common-law duties are never requirements within the meaning of § 360k and that the statute therefore never pre-empts common-law actions. *Id.* at 502-03.

Justice Bryer, writing separately, noted that "[o]ne can reasonably read the word 'requirement' as including the legal requirements that grow out of the application, in particular circumstances, of a State's tort law." *Id.* at 504. Bryer used the example of a federal regulation of hearing aids requiring a two-inch wire, and a state regulation requiring a one-inch wire. The state regulation would clearly be pre-empted, Bryer reasoned, therefore a jury award of damages based on the one-inch wire would also be pre-empted. *Id.*

The Supreme Court has revisited its holding in *Lohr* to insinuate that the term "requirement" in the MDA applies to tort claims as well as particular state statutory "requirements." *See Geier v. American Honda Motor Corp.*, 529 U.S. 861, 867 (2000) ("a majority of this Court has said that . . . a provision that uses the word 'requirements'—may well expressly pre-empt similar tort actions."). (Emphasis added) (citing *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 502-04 (1996) (plurality opinion); *id.* at 503-05 (Breyer, J. concurring in part and concurring in judgment); *id.*, at 509-12 (O'Connor, J. concurring in part and dissenting in part)); *American Honda Motor Corp.*, 529 U.S. 861, 897 (2000) (Stevens, J. dissenting) ("And in *Medtronic v. Lohr*, we recognized that the statutory reference to 'any requirement' imposed by a State or its political subdivisions may include common-law duties.") (citations omitted) (emphasis added). Despite this language, there has been no explicit holding by the Supreme Court, in the medical device realm, that any particular common law claim has constituted a "requirement ."

Equally difficult has been determining what constitutes the federal requirement. At least two approaches have been put forth. Some courts have applied a process-oriented definition to the term "requirement." *See, e.g., Mitchell v. Collagen Corp.*, 126 F.3d 902 (7th Cir.1997). Those courts reason that the PMA process itself, without more, constitutes the "requirement" mentioned in the statute. Another approach is to look at the device specific edicts from the FDA, and consider those edicts the "requirements" of 360k.

Some Courts have held that the PMA process itself is a federal "requirement" imposed by the MDA. *See Mitchell*, 126 F.3d 902 (holding that unlike the 510k process, the PMA process can constitute the sort of specific

federal "requirement" that can have preemptive effect under the MDA); *Martin v. Medtronic, Inc.*, 254 F.3d 573 (5th Cir.2001) (same). There is a division of authority, however, and the Eleventh Circuit has reached the opposite conclusion. *Goodlin v. Medtronic, Inc.*, 167 F.3d 1367 (11th Cir.) *reh'g* and *reh'g en banc* denied (1999) (holding that the PMA process itself is not a "requirement" and reasoning that the ordinary construction of the language of 360k and use of the term "requirement" in the broader statutory context and the FDA regulations contemplate the imposition of some identifiable precondition that applies to the device in question); *Woods v. Gliatech, Inc.*, 218 F.Supp.2d 802 (W.D.Va.2002) (holding that PMA approval represents only a finding that the device manufacturer has reasonably assured the FDA of the safety and effectiveness, and also finding that PMA approval does not provide any indication of what, if any, specific substantive requirements the FDA may have applied to reach that result); *Webster v. Pacesetter, Inc.*, 171 F.Supp.2d 1, 19 (D.D.C.2001) (rejecting argument that PMA process amounts to a "requirement"); *Quillin v. American Hosp. Supply Co.*, 1997 WL 382095 (N.D.Okl., March 31, 1997) (PMA process does not constitute a "requirement" for the purpose of determining whether a plaintiff's state common law claims are preempted). The Supreme Court has not addressed the issue.

Prior to *Lohr*, the Eighth Circuit had held that the PMA process itself constituted a "requirement." *See Martello v. Ciba Vision Corp.*, 42 F.3d 1167 (8th Cir.1994). However, in *Brooks v. Howmedica*, the Eighth Circuit, sitting *en banc*, retreated from that broad holding. *See Brooks v. Howmedica*, 273 F.3d 785, 795 (8th Cir.2001), *cert. denied*, 535 U.S. 1056 (2002) (noting that the *Martello* holding "requires some modification"

to be consistent with the Supreme Court's decision in *Lohr*). The *Brooks* Court did not hold that the PMA process itself amounts to a requirement. Instead, the *Brooks* Court carefully compared the plaintiff's claims with the federal requirements and determined that "[t]he failure to warn claim [plaintiff] Brooks seeks to assert could impose state requirements which conflict or interfere with these federal directives. Because these 'particular state requirement[s] threaten[ ] to interfere with . . . specific federal interest[s],' *Lohr,* 518 U.S. at 500, 116 S.Ct. 2240, Brooks' claim is preempted by the MDA." *Id.* at 798 (alteration and internal quotation in original).

B. Applying express preemption

1. *Medtronic, Inc. v. Lohr*

In *Medtronic, Inc. v. Lohr,* the Supreme Court first discussed whether the MDA preempts particular common law tort claims. 518 U.S. 470 (1996). The plaintiff in *Lohr* had received a pacemaker (a Class III device) that had been approved under the 510k process. Plaintiff asserted claims of negligence and strict liability against the manufacturer, alleging defendant had failed to use reasonable care during production. The Court, in a plurality opinion, held that none of plaintiff's claims were preempted. Specifically, the Court held that the MDA does not preempt state or local requirements that are equal to, or substantially identical to, requirements imposed under federal law. Similarly, the Court held that plaintiff's claims were not preempted to the extent that they alleged that the manufacturer failed to comply with duties equal to, or substantially identical to, federal requirements.

In response to the defendant's preemption argument, the *Lohr* Court emphasized that it would be "to say the

least, 'difficult to believe that Congress would, without comment, remove all means of judicial recourse for those injured by illegal conduct,' and it would take language much plainer than the text of § 360k to convince us that Congress intended that result." *Id.* at 484 (quoting *Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238, 251 (1984)). The Court went on to note that, "[n]othing in 360k denies [States] the right to provide a traditional damages remedy for violations of common-law duties when those duties parallel federal requirements." *Id.* at 495.

Lohr generated confusion as the circuit courts attempted to discern its specific holding, and apply it in subsequent cases, including cases in which plaintiffs were injured by devices that had been approved through the full PMA process, and cases in which plaintiffs pled alternate theories of liability. *See Kemp,* 231 F .3d at 221 (noting that "[C]ourts of appeals that have confronted the issues of preemption arising under the MDA have struggled mightily with *Lohr's* language in the effort to discern its holding" and further noting that "[t]his appeal presents fractious issues which have sharply divided the various circuit courts which have considered them."). *Compare Kemp,* 231 F.3d 216 (granting summary judgment to pacemaker manufacturer on preemption grounds) *with Goodlin v. Medtronic, Inc.,* 167 F.3d 1367 (11th Cir.1999) (facts and legal theories almost indistinguishable, but refusing to find plaintiff's claims preempted).

2. *Brooks v. Howmedica*

In *Brooks v. Howmedica,* 273 F.3d 785 (8th Cir.2001), *cert. denied,* 535 U.S. 1056 (2002), the Eighth Circuit, sitting *en banc,* reversed its panel decision, and denied relief to a former orthopedic surgical nurse who had

been injured by repeated on-the-job exposure to toxins released as she mixed bone cement.[8] The *Brooks* court held that plaintiff's claims of negligent failure to warn and failure to comply with federal labeling regulations were expressly preempted.[9] In reaching this conclusion, the court discussed the extensive regulation to which defendant was subject, and noted that the approval process "included review by the FDA of the proposed design and content for all Simplex labels" and that "the FDA drafted the language that was used in the package insert." The court also emphasized that the case involved "ascertainable requirements" taking the form of "a series of mandates regarding the label" issued by the FDA. Under the *Brooks* analysis, such mandates amount to the federal "requirement" with which state "requirements" must not conflict.

The *Brooks* court articulated a "three-step test" to determine if a plaintiff's state law claim is preempted-first, discern the federal requirement imposed on a medical device manufacturer; next, determine the state requirement; finally compare the two to see if there is conflict. *Id.* at 794 (*"Lohr* instructs that state requirements—including common law duties-are preempted to the extent that they interfere with specific federal

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[8] It is noteworthy that the plaintiff in *Brooks* was in a different position than the typical plaintiff—that is, plaintiff Brooks was not a recipient of the medical device at issue, rather, her injuries were caused by mixing the bone cement to prepare the device for surgery.

[9] The Eighth Circuit mimicked the Supreme Court in declining to address the "other" preemption category—that is, the Supreme Court in *Buckman* stated in a footnote that because it found plaintiffs' claims impliedly preempted, it would not address express preemption. In *Brooks* the Eighth Circuit, also in a footnote, noted that "because we find express preemption, we do not address any potential issue of implied preemption." *Id.* at 792 n. 7.

requirements. The state and federal restrictions must be 'carefully compar[ed]' to ascertain whether there is interference between them—that being the 'overarching concern' of the test articulated by Justice Stevens and joined in by Justice Breyer.") (emphasis added) (quoting *Lohr*, 518 U.S. at 500).

C. Implied preemption - *Buckman Co. v. Plaintiffs' Legal Committee*

After *Lohr*, the Supreme Court next examined the issue of preemption in the MDA context in *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001). In *Buckman*, plaintiffs injured by orthopedic bone screws brought suit alleging that defendant, a regulatory consultant, had made fraudulent representations to the FDA in order to obtain approval to market the devices. The *Buckman* Court declined to address whether express preemption applied, holding that plaintiffs' "fraud on the FDA" claims were impliedly preempted. The Court noted that the FDA itself is charged with policing fraud on it and has a variety of enforcement options that allow it to make "a measured response to suspected fraud." *Id.* at 350. Therefore, the state fraud on the FDA claims conflicted with the FDCA—specifically, permitting plaintiffs' claims would conflict with the FDA's responsibility to police fraud consistently with its judgment and objectives.

In *Buckman*, despite the express preemption provision of 360(k) the Court found implied preemption applicable. In doing so, the Court did not clarify the confusion surrounding the appropriate use of implied versus express preemption. In fact, the Court specifically "express[ed] no view on whether the[ ] claims [were] subject to express pre-emption under 21 U.S.C. § 360k." *Id.* at 348 n. 2. The failure to address whether both types

of preemption could apply is significant, because, until *Buckman,* an oft-cited rule was that where express preemption applied, courts would not use the implied preemption theory. *See Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 517 (1992) ("Congress' enactment of a provision defining the pre-emptive reach of a statute implies that matters beyond that reach are not preempted.") (citations omitted). The *Buckman* Court also chose not to specify whether preemption analysis differs depending on the process through which the at-issue devices was approved (510k, PMA, or IDE).

Though instructive,[10] *Buckman* is distinguishable on several important grounds. First, the device approved in *Buckman* was approved via the 510k process, not the PMA/PMA Supplement process. In addition, the bone screws at issue in *Buckman* were being used "off-label" (they were approved for use in long bones, but were being used in back surgeries), an important distinction because Congress has repeatedly and explicitly noted that the FDA is not designed to interfere with practice of medicine. Plaintiffs in *Buckman* made only "fraud on the FDA claims." The Court specifically noted that states do not have a traditional interest in policing fraud on government agencies. The Court also emphasized that the MDA set up a comprehensive scheme for policing fraud, and that consumers could petition the FDA to take action against suspected wrongdoing. The harm complained of in *Buckman* was the fraud itself, as allegedly perpetrated

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[10] Defendant, while distinguishing a case from the Tenth Circuit, suggests that where a different method of approval is at issue (such as the 510k approval), the case "does not inform the issues before this Court." (Def. Brief at 10 n. 5.) The Court disagrees with this characterization, and finds useful those cases that involve other types of FDA approval, including *Buckman* and *Oja v. Howmedica, Inc.*, 111 F.3d 782, 789 (10th Cir.1997).

by the consulting group, not the plaintiffs' personal injuries. In fact, the manufacturer of the bone screws had settled with plaintiffs before the case was appealed to the Supreme Court. *See* Daniel W. Sigelman, *Is Fraud-on-the-FDA a Dead Letter After Buckman v. Plaintiffs' Legal Committee?*, 2 ATLA-CLE 2483 (2001) (noting that AcroMed Corporation, maker of the devices at issue, settled after Third Circuit's opinion). The remaining defendant was an FDA consultant who was not responsible for the design of the device, only for the manner in which the application was presented to the FDA.

III. Discerning the Federal "Requirements"

The parties understandably dispute the fundamental issue of what constitutes "requirements" of federal law in this case. This dispute is predictable, given the conflicting authority in both federal and state courts, as discussed above. The Court notes theoretical and practical difficulties in the "process" approach. Accepting the "process" argument-that the PMA Supplement process itself is a requirement-makes it difficult as a practical matter to find any claim that is not preempted. On a more theoretical level, this broad immunity is not consistent with Congressional intent in enacting the MDA, *see generally Lohr*, 518 U.S. at 490-92 (discussing congressional history), and is also not consistent with the presumption against preemption in areas of traditional state control (such as health and safety). *See id.* at 475 ("Throughout our history the several States have exercised their police powers to protect the health and safety of their citizens."). Despite these shortcomings to the process approach, a majority of federal courts have held that the PMA/PMA Supplement process itself is a

"requirement." *See supra; see also Am. L. Prod. Liab.*3d § 91:16.

The Court finds that, given the language of § 360k and the implementing regulations,[11] the Supreme Court's rationale in *Lohr,* and the Eighth Circuit's reasoning in *Brooks v. Howmedica,* PMA Supplement approval, without more, is not necessarily a "requirement" of federal law. The submission of a product to the FDA for pre-market supplement approval does not, in itself, amount to a specific federal requirement meriting preemptive effect. Instead, the Court will inquire whether the FDA, in this instance, has promulgated any ascertainable precondition to regulatory approval. The Court will carefully examine the potential "federal requirements" and then compare those requirements to the relevant state laws.[12]

IV. Discerning the State Requirements and Comparing for Conflict

A. Strict liability and negligence claims

Plaintiffs allege that the Silzone valve was defective in design and/or formulation in that when the valves left

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[11] 21 C.F.R. § 808.1(d) "State or local requirements are preempted only when the Food and Drug Administration has established specific counterpart regulations or there are other specific requirements applicable to a particular device under the act, thereby making any existing divergent State or local requirements applicable to the device different from, or in addition to, the specific [FDA] requirements."

[12] The Court will address only the "main" claims common to the majority of plaintiffs. By not addressing a particular claim, the Court is not expressing an opinion on whether that ancillary claim would amount to a conflicting "requirement." However, defendant is not entitled to summary judgment on such claims, because defendant did not meet its burden of establishing that such claims conflict with a federal requirement.

defendant's hands the risks exceeded the benefits. Alternately, plaintiffs argue that the valves were defective in design or formulation in that they were more dangerous than an ordinary consumer would expect when used in their intended or reasonably foreseeable manner. Plaintiffs also allege the valves were defective due to inadequate warning, and that defendant failed to provide adequate post-marketing warnings. In addition, plaintiffs allege the valves failed to conform to the representation of defendant (in that they were not safe for use by consumers), and plaintiffs allege defendant failed to adequately test the valves.

Defendant argues that these claims are necessarily preempted because the FDA approved the device, and any inquiry into the approval process is forbidden "second-guessing" of the FDA. Plaintiffs argue that these claims are not pre-empted because the claims do not rely on any state "requirement" different from any federal requirement. Plaintiffs suggest that because there was no "requirement" to continue selling Silzone after its safety was called into question, plaintiffs' strict liability (and negligence) claims cannot be preempted.

Device manufacturers are never "required" to sell devices, and therefore it seems that plaintiffs' first argument would totally eliminate preemption—a result that clearly is incorrect. Plaintiffs' next argument, however, is more persuasive. Plaintiffs note that the FDA encourages voluntary recalls and unilateral changes to warning labels. Although the *Brooks* Court rejected an argument premising liability on the failure to update a warning, plaintiffs' argument is distinguishable. In *Brooks*, the Eighth Circuit examined the plaintiff's evidence to discern (1) whether the FDA was aware of that particular risk when approval to the warning language was granted and (2) whether that risk was scientifically established

either at the time of approval, or at the time the suit was brought. This inquiry implies that if the FDA had not been aware of the risk, plaintiff Brooks' failure to warn claim would not have been preempted. Applying that reasoning here, plaintiffs would have to establish that defendant knew of the particular risks during the PMA Supplement process, and that the risk is scientifically valid. Plaintiffs claim to have evidence of both, and point to specific facts in the record demonstrating a dispute of material fact.[13] Defendant has not, therefore, established that plaintiffs' strict liability failure to warn claims are pre-empted and summary judgment is inappropriate.[14]

Although the *Brooks* decision did not address a claim for design defect, the Court applies a similar rationale to deny defendant's motion for summary judgment as to those claims. As the Eighth Circuit explicitly stated in *Brooks*, a claim alleging failure to comply with FDA regulations is not preempted, because such a claim

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[13] Plaintiffs claim both pre-approval and post-approval evidence. Plaintiffs point to evidence that defendant misrepresented the results of animal tests to the FDA because defendant failed to report the death of one of the subject animals. In addition, plaintiffs cite public reports from the medical community of high rates of stroke and other thromboembolic events, as well as allegedly high explant patterns. Plaintiffs claim these facts establish knowledge on defendant's part that the valve was problematic, yet defendant did not report the problems to the FDA.

[14] Defendant's argument would allow medical device manufacturers to wrongfully withhold data from the FDA, gain PMA or PMA supplement approval, and then be completely immune from liability based on that approval. This cannot be what Congress had in mind when it enacted the MDA because, in its judgment, medical device manufacturers needed to be more strictly regulated. *See Lohr*, 518 U.S. at 587 (noting that in the judgment of Congress the medical device industry needed more stringent regulation).

imposes no requirements different from or in addition to federal requirements. *Brooks*, 273 F.3d at 798-99. Pre-emption was nonetheless appropriate in the *Brooks* case, however, because the Eighth Circuit determined that plaintiff did not make such a claim. In contrast, plaintiffs here claim, and present evidence, that defendant "violated federal regulations . . . failed to meet regular reporting requirements, failed to report a known hazard to the FDA, [and] failed to comply with federal law in other respects." *Id.* at 799. Therefore, to the extent that plaintiffs' negligence and defective design claims hinge on violations of FDA requirements, the claims are not preempted, and summary judgment is not appropriate.

B. Implied and Express Warranty

Plaintiffs allege that defendant breached the implied warranty because the Silzone valve was not fit and safe for its intended use, the defects were present when the product left defendant's hands and the valves were defective, unmerchantable and not fit for their intended purpose. To support their argument that the implied warranty claim is not pre-empted, plaintiffs point to section 808 of chapter 21 of the C.F.R. which notes that "[t]he following are examples of State or local requirements that are not regarded as preempted . . . requirements of general applicability where the purpose of the requirement relates either to other products in addition to devices (e.g., requirements such as . . . the Uniform Commercial Code (warranty of fitness))." (Emphasis added.) Since many states, including Minnesota, have adopted the U.C.C. implied warranty provision, it appears that claims premised on the U.C.C. should survive preemption motions. *See Duvall v. Bristol-Myers-Squibb Co.*, 103 F.3d 324, 330, n. 5 (4th Cir.1996) ("Although the [Supreme] Court did not address a claim

for breach of implied warranty in *Medtronic [v. Lohr]*, we nevertheless determine that the reasoning of that decision requires a conclusion that state-law claims for breach of implied warranties are not preempted by § 360k(a)."). *But see Mitchell v. Collagen Corp.*, 126 F.3d 902, 915 (7th Cir.1997) ("If the [plaintiffs] meant to allege an implied warranty, it is preempted.").

Similarly, plaintiffs cite several cases in which courts have explicitly held that express warranty claims are not preempted. Those cases seem correctly decided and the Court agrees that express warranty claims are not preempted, at least to the extent that the defendant makes express warranties in addition to the language (warranties or warnings) required by the FDA. *See Mitchell*, 126 F.3d at 915 ("As we noted in our earlier opinion, [express] warranties arise from the representations of the parties and are made as the basis of the bargain between them. A state judgment based on the breach of an express representation by one of the parties does not necessarily interfere with the operation of the PMA, and therefore we cannot say that such a cause of action is preempted."). *See also Steele v. Depuy Orthopaedics, Inc.*, 2003 WL 22779079 at (D.N.J. Nov. 20, 2003) (denying defendant's motion for summary judgment on preemption grounds as to plaintiff's breach of express warranty claims).

As evidence of particular express warranties that (allegedly) were breached, plaintiffs point to, among other things, an advertisement for Silzone which states, "With over 30,000 implants St. Jude Medical heart valves with Silzone coating continue our tradition of excellent clinical performance." Plaintiffs then note that in deposition, St. Jude employee Dr. Guzik admits that the "tradition of excellent clinical performance" was questionable. Plaintiffs argue this is a clear-cut example

of a breach of express warranty. Plaintiffs also assert, and support with deposition testimony, that St. Jude sales representatives represented to heart surgeons that the Silzone valves were superior to the Masters Series because of the anti-microbrial properties of the silver in the Silzone.[15] Such a representation was expressly forbidden by the FDA. St. Jude disputes that it made such representations, and points to statements by St. Jude managers to that effect. This disagreement highlights the disputed material facts. Plaintiffs have pointed to specific, admissible evidence raising disputed issues of material fact on these claims. Therefore summary judgment on pre-emption grounds must be denied as to the breach of warranty claims.

C. Inadequate warnings and labeling

Plaintiffs call this an "easy call" arguing that because Minnesota's duty to warn "requirements" mirror product manufacturers' duties under the FDCA and the FDA, there is no conflict. The trouble with plaintiffs' analysis is that the FDA, at least initially, determined that the labeling constituted an adequate warning. In fact, the FDA drafted some of the language, and approved all of the language.

Plaintiffs' argument continues—"despite knowledge [of risks] SJM never made or even proposed a single

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[15] For example, a St. Louis thoracic surgeon averred that he implanted approximately fifty Silzone valves "because of its asserted anti-bacterial and anti-infection properties." This understanding, he continues, "came in significant part from statements made to me by a sales representative of St. Jude Medical . . . [who] informed me that the Silzone valve was an improvement over the existing St. Jude Master's Series valve because the Silzone coating on the valve sewing cuff would greatly reduce the incidence of post-surgery infection." (Plaintiffs' Appendix at Volume VI, Exhibit 21).

change to the Silzone labeling." At first blush, this argument is identical to that rejected by the Eighth Circuit in *Brooks*. However, the plaintiff in *Brooks* could not show (or simply failed to show) that the FDA was unaware of the risks when the labeling was approved. Here, plaintiffs argue that they can demonstrate that the FDA was unaware of certain risks as the label language was updated. Defendant argues that plaintiffs' claims are nonetheless preempted, because to prove that the FDA was unaware of a given risk, plaintiffs will essentially have to prove fraud on the FDA-the inquiry rejected in *Buckman*. Defendant apparently would have the Court read *Buckman* so as to preempt any and all claims in which any inquiry into the FDA regulatory process is necessary.

It is difficult to accept such an expansive reading of *Buckman*, and such a reading would be difficult, if not impossible, to reconcile with the decision announced in *Lohr*. In addition, the *Brooks* Court had the benefit of the *Buckman* opinion, and nonetheless reasoned that the result might be different had plaintiff shown that the FDA was unaware of certain information. The Supreme Court in *Buckman* was addressing a cause of action emanating exclusively from federal regulations. This case does not present such a limitation. The critical distinction between *Lohr* and *Buckman* is not that a court or jury would have to examine what the FDA knew, and when it knew it. Instead the meaningful distinction is a fundamental difference in the very source of the cause of action. That is, in *Lohr*, the cause of action was based in traditional state tort law; in sharp contrast, the cause of action asserted in *Buckman* depended entirely on the regulatory relationship between the federal government and the FDA. In that dispositive way, the instant case is more similar to *Lohr*, and entirely unlike *Buckman*. In this

case, the inadequate labeling and failure to warn claims are based on traditional tort causes of action—causes of action that have normally been the exclusive province of states. For that reason, *Buckman* does not require preemption of these claims.[16]

Similarly, *Brooks* does not dictate a result in defendant's favor. Unlike the plaintiff in *Brooks*, the plaintiffs here have alleged, and have supported with specific evidence, that the FDA was not aware of the risk that the Silzone valve presented. In short, plaintiffs have raised disputed issues of material fact such that their inadequate warning and labeling claims survive summary judgment on the ground of preemption.

D. Consumer fraud & deceptive trade practices statutes

Like state law requirements under the U.C.C., the applicable regulation expressly states that claims under state unfair trade practices are not preempted. 21 C.F.R. § 808(d). Citing *Buckman*, defendant argues that plaintiffs' consumer fraud and deceptive trade practices claims are really "fraud on the FDA claims" in disguise, and are therefore preempted. Again, the Court does not find that *Buckman* extinguishes plaintiffs' claims at this stage of the litigation. Instead, the Court finds this case

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[16] Legal commentators have made a similar distinction. *See, e.g.*, Thomas O. McGarity, *Beyond Buckman: Wrongful Manipulation of the Regulatory Process in the Law of Torts*, 41 Washburn L.J. 549, 572 (2002) ("Under *Medtronic [v. Lohr]* and its predecessors, plaintiffs should ordinarily be able to base actions against manufacturers of risky products on traditional common law negligence and strict liability theories without fear of preemption. As cases based upon negligence and strict liability go forward, evidence of attempts by the defendant to manipulate the regulatory process through fraudulent or misleading means should be admissible even if wrongful manipulation may not support an independent claim for relief.").

more analogous to *Dawson ex rel. Thompson v. Ciba-Geigy Corp., USA*, 145 F.Supp.2d 565 (D.N.J.2001). In that case, the Court rejected defendant's preemption argument, noting:

> Plaintiffs' Complaint here does not allege a claim of "fraud on the FDA," but rather alleges that Defendants deceived the public, including Plaintiffs. The Supreme Court in *Buckman* expressly distinguished "fraud on the FDA" claims from other state tort claims for fraudulent labeling, such as those that the Court had previously addressed in *Medtronic v. Lohr*, 518 U.S. 470 (1996). *Buckman*, 121 S.Ct. at 1020. . . . *Buckman* thus clarified that traditional state tort law claims (even those which parallel FDCA requirements) are not necessarily preempted by the FDCA and are not necessarily the same as "fraud on the FDA" type claims. *Id.* Unlike the claims in *Buckman*, a finding of a violation of the FDCA is not a necessary element of Plaintiffs' claims, which rely on traditional state tort principles. Plaintiffs are not claiming a violation of the FDCA; their claims are confined to traditional state tort and fraud claims, similar to those in *Medtronic*.

Id. at 573. The Court finds that reasoning persuasive, and therefore denies defendant's pre-emption motion on the consumer fraud and deceptive trade practices claims.

E. Medical monitoring

In general, a medical monitoring plaintiff must establish exposure to a hazardous substance; that as a proximate result of exposure, plaintiff suffers a significantly increased risk of contracting a serious latent disease; that increased risk makes periodic diagnostic medical examinations reasonably necessary, and that monitoring

and testing procedures exist which make the early detection and treatment of the disease possible and beneficial. The parties' briefing did not address whether medical monitoring claims impose requirements different from or in addition to those imposed by federal requirements, and the Court determines that such claims do not. Therefore, defendant's motion for summary judgment is denied as to plaintiffs' medical monitoring claims.

V. Drug, Device, or Both

Plaintiffs also assert that they have raised a disputed issue of material fact as to whether the valve is a device, or is a combination drug and device. This distinction is important because the express preemption principles and case law discussed above do not apply to combination products or to drugs (§ 360k by its terms applies only to devices). Plaintiffs base this argument on their experts' opinions that the silver sewn into the valve interacts with the body more like a drug than a device. Plaintiffs assert that the FDA never determined that the valve is a device, rather than a drug, but that even if such a determination had been made, the Court is not bound by the FDA's determination. *See Tarallo v. Searle Pharmaceutical, Inc.*, 704 F.Supp. 653, 658 (D.S.C.1988) (reasoning that because Congress defined the terms "drugs" and "device" the Court is not bound by an administrator's determination); *see also Callan v. G.D. Searle & Company*, 709 F.Supp. 662, 666 (D.Md.1989) (finding that Copper 7 IUD was drug due to release of copper ions).

Defendant briefly addresses this argument, and states the FDA expressly considered the drug/device issue and classified the valve as a device. The Court reviewed the exhibits defendant identified, and from those exhibits, it appears that the FDA *considered* the drug or device issue. In particular, one exhibit defendant identifies is a

portion of minutes from a June 1998 meeting, apparently of the Circulatory Systems Devices Panel of the FDA. Def. Appendix C, tab 32. That excerpt includes a discussion during which the drug/device distinction was addressed, but, at least in the portion submitted to the Court, there does not appear to be a conclusion or consensus reached. Defendant also suggests that all of Appendix C supports its argument that the FDA expressly determined that the valve is a device. The Court carefully reviewed the documents submitted in Appendix C, and did not uncover any indication that the FDA explicitly determined that the valve is a device, rather than a drug. The Court notes, however, that Appendix C does contain many instances of defendant making that assertion to the FDA, and the FDA continually referred to the valve as a device.

The Court owes no deference to an FDA "classification" where it is made simply for "administrative convenience" and does not reflect the considered view of the agency. *See Tarallo,* 704 F.Supp. at 658. The Court finds plaintiffs' argument that the valve more closely resemble a drug/device combination to be intuitively persuasive. However, because the Court finds that plaintiffs' claims are not pre-empted and this drug/device issue requires more extensive analysis, the Court will not decide at this time whether the heart valve with Silzone coating is a drug, a device or a combination.

VI. What approval? 510k or PMA Supplement

Plaintiffs finally argue that because the approval process here was more like the abbreviated 510k-equivalence process than the PMA Supplement-safety process, preemption should not apply. *See Brooks,* 273 F.3d at 794 ("Section 510(k) approval is a mere grant to market; it imposes no "requirements" of its own.") (Citing *Lohr,*

518 U.S. at 493). Plaintiffs suggest that the Court simply needs to determine that the FDA never made a determination of the efficacy of the Silzone coating.

The FDA, at least ostensibly, approved the valve via the PMA Supplement. (March 24, 1998 Letter from Susan Alpert, Director, Office of Device Evaluation stating "The Center for Devices and Radiological Health (CDRH) of the [ ] FDA has completed its evaluation of your premarket approval application (PMA) supplement."). On the other hand, it is clear that the FDA never determined that the Silzone coating was "effective." In fact, the FDA explicitly precluded defendant from making claims regarding the efficacy of the Silzone coating. *Id.* ("[T]he labeling of the device must not contain or imply any claims that the Silzone Coating is effective in reducing the incidence of endocarditis."). Equally clear, nonetheless, is that the valve itself continued to be considered effective as a heart valve. The parties ask the Court to determine if issuing a PMA Supplement approval without making a finding of efficacy, invalidates the approval, transforms the approval into 510(k) approval, or is an abuse of agency discretion.

A separate, but related argument is that the approval, whichever approval it was, was lost when defendant failed to comply with FDA guidelines, or if not at that point, at least once the product was voluntarily recalled. "Please comply with the above guidelines. We do not want to do anything that will jeopardize our own FDA approval." (Memorandum from Hosek to U.S. Sales Force at Plaintiffs' Appendix Vol. VI, Ex. 79.)

The FDA classified St. Jude's actions as "a recall." The Administration noted, "We are assigning recall numbers to [Silzone valves] . . . We are classifying the firm's actions as a voluntary recall. We consider the devices to be adulterated and misbranded." (March 20,

2000, Memorandum from Cardiovascular and Neurological Devices Branch at Plaintiffs' Appendix Vo;. VI, Ex. 100.) Similarly, a March 22, 2000 letter from Edwin Dee to St. Jude noted, "We agree with your firm's decision to recall [listing of specific device identifying numbers] . . . We have reviewed your action and conclude that it meets the formal definition of a 'Recall'. This is significant, as your action is an alternative to a Food and Drug Administration legal action to remove the defective products from the market." (Plaintiffs' Appendix Vol. V, Ex. 24.)

Defendant suggests that this letter is "out of context" and that the Silzone valve in fact has never been recalled (specifically, counsel for St. Jude stated at oral argument that "[T]he adulterated and defective language that the plaintiffs pick on from the correspondence is drawn out of context. It doesn't represent any regulatory finding or conclusion."). The Court hesitates to characterize defendant's argument too harshly, however, it is difficult to read the FDA's March 20, 2000 and/or March 22, 2000 correspondence and find any ambiguity, regardless of context. The FDA clearly indicates that the device is "adulterated and misbranded." The recall is significant because it is "an alternative to [FDA] legal action to remove the product from the market." Despite defense counsel's arguments, St. Jude appears to recognize that the Silzone valve is not marketable absent additional approval from the FDA. *See Affidavit of Alan Flory* at Plaintiffs' Appendix, Vol. II, Tab. 2(A) page 258. (Q: "The fact that the PMA Supplement has not been withdrawn doesn't mean that you're perfectly free to go out and market this product again, unless FDA says you can do it. Isn't that fair?" A: "That's true. . . . Unless we put in a PMA supplement and notify [the FDA] that we

have the clinical data that we said we would gather before we put it back on the market.")

The Court finds persuasive plaintiffs' argument that the Silzone valve no longer has FDA approval. At this time, however, the Court need not determine how the withdrawal of approval impacts plaintiffs' claims. Similarly, the Court will not resolve whether the Silzone valve's approval was via the PMA supplement or was 510k approval, because the Court has found that plaintiffs' claims are not pre-empted. The Court will not scrutinize such an involved issue without the benefit of thorough briefing on this specific question. The Court's research has revealed that plaintiffs' argument regarding types of approval (PMA versus 510k) is not novel, but the Court has been unable to find a reported decision in which a court analyzes the method of approval to determine independently whether the approval was PMA or 510k. *See, e.g., Steele v. Depuy Orthopaedics, Inc.*, 2003 WL 22779079 at (D.N.J. Nov. 20, 2003) (acknowledging plaintiffs' argument that the approval at issue was more akin to the abbreviated 510k, and apparently rejecting the argument, but not discussing the issue).

MOTIONS TO STRIKE

I. Defendant's motion to strike affidavits of plaintiffs' three experts

Defendant moves to strike the affidavits of Gregory Wilson, Devin Healy, and Suzanne Parisian, arguing that the expert reports violate "fundamental rules of evidentiary admissibility." Defendant asserts four "compelling reasons" to strike the affidavits, including (1) the opinions are irrelevant, (2) the expert's testimony is not the proper subject of expert opinion under controlling

law, (3) the opinions are simply legal conclusions "recast as expert opinion," and (4) the experts are not qualified.

For the purposes of this motion, the Court denies the motion to strike. The material is relevant, and the Court assures defendant that the Court will reach its own conclusions regarding the law and will not be misled by plaintiffs' experts. The Court might well be more cautious in allowing a jury to consider such opinions. Finally, the Court finds that the experts are adequately qualified given each expert's education, training and experience.

II. Plaintiffs' Motion to Strike the Affidavits of Alan Flory and Diane Johnson.

Flory is an employee of St. Jude Medical. Johnson is a former FDA employee who is presented as having expertise in the field of heart valve regulation and the PMA process. Plaintiffs object on the grounds of hearsay and lack of personal knowledge. Plaintiffs note that in deciding a motion for summary judgment, the Court may not consider affidavits that do not satisfy the requirements of Fed.R.Civ.P. 56(e).

Plaintiffs argue that the information in Flory's affidavit is based on hearsay. In addition, plaintiffs suggest that Flory admitted during deposition that he has no personal knowledge that St. Jude complied with every applicable FDA regulatory requirement as he averred. The basis for the objection to the Johnson affidavit appears to be lack of personal knowledge.

The Court denies the motion to strike for purposes of this summary judgment motion. Although the Court must not rely on evidence which would be inadmissible, it is not necessary to strike either affidavit. Plaintiffs have preserved their objections, and the Court can sift through the affidavits to determine what portions, if any, would

be inadmissible and therefore will not be considered for the purposes of summary judgment. It appears to the Court that Johnson is offered as an expert, and therefore the personal knowledge objection is inapplicable.

III. Plaintiffs' motion to strike the attachments to defendant's reply brief

The Court granted defendant a significant page and time extension for its reply brief. Defendant used its full page allotment, and also attached additional argument, in the form of "charts" as exhibits. These exhibits are improper, and given the Court's reasonableness in granting the page and time extension, the Court finds defendant's additional argument in the guise of "exhibits" unfortunate. The Court therefore strikes the argumentative portions of the "charts" (specifically, the portions preceding the numbered tabs). However, the charts also serve as a table of contents, and the Court will continue to use the table of contents portion.

ORDER

Based upon the foregoing, the submissions of the parties, the arguments of counsel and the entire file and proceedings herein, IT IS HEREBY ORDERED:

1. Defendant's motion for summary judgment [Docket No. 67] is DENIED;

2. Defendant's motion to strike the affidavits of Gregory John Wilson, Kevin E. Healy, and Suzanne Parisian [Docket No. 219] is DENIED.

3. Plaintiffs' motion to strike the affidavits of Alan R. Flory and Diane Johnson [Docket No. 208] is DENIED.

4. Plaintiffs' motion to strike appendices to St. Jude's reply in support of motion for summary judgment [Docket No. 223] is GRANTED in part and DENIED in part as described above.

IN THE DISTRICT COURT OF
HARRIS COUNTY, TEXAS
157th JUDICIAL DISTRICT

Filed April 20, 2007
(Trial Court: 151st Dist. Court of Harris County,
Cause No. 2005-58543)

RUBY LEDBETTER

—v.—

MERCK & CO., INC.

Order Granting Defendant's Motion for Partial Summary Judgment And Granting Expedited Appeal

Defendant Merck & Co., Inc. ("Merck") has filed a no evidence motion for partial summary judgment on plaintiff's warning claims. This motion is based on a 2003 Texas statute governing FDA approved warnings. TEX. CIV. PRAC. & REM. CODE ANN. § 82.007. Merck argues that § 82.007 is preempted by federal law. For reasons stated, the motion is granted.

1. Background

Vioxx (known generically as rofecoxib) is a NSAID (non-steroidal anti-inflammatory drug). This class of drugs includes over the counter medications, such as Advil (ibuprofen) and Aleve (naproxen) and a variety of prescription medicines. NSAIDS work by inhibiting cyclo-oxygenase (COX), an enzyme that stimulates synthesis of prostaglandins, which are chemicals produced in the body that promote certain effects.

In the early 1990s, scientists discovered that the COX enzyme was composed of two forms. COX-1 affects the synthesis or production of prostaglandins responsible for protection of the stomach lining; COX-2 stimulates the prostaglandins that cause pain and inflammation. This belief led to the hypothesis that a selective NSAID, designed to inhibit COX-2, but not COX-1, could offer pain relief without the risk of fatal or debilitating gastrointestinal perforations and ulcers. This led Merck to begin the development of such a drug, which became known as a COX-2 inhibitor. Vioxx is a COX-2 inhibitor.

In December 1994, Merck submitted an Investigational New Drug Application to the FDA seeking approval to conduct studies to test the safety of Vioxx to treat osteoarthritis, rheumatoid arthritis, and pain. In November 1998 Merck submitted a New Drug Application for Vioxx. The FDA reviewed the Merck submission and, as well, convened an Advisory Committee to review the data and make recommendations. On May 20, 1999, the FDA approved Vioxx for sale in the United States.

Vioxx was subjected to a number of studies and trials, including VIGOR, APPROVe, and others. APPROVe was a randomized clinical trial that compared Vioxx to a placebo. The APPROVe study indicated that the use of

Vioxx increased the risk of cardiovascular thrombotic events such as myocardial infarctions.

On September 30, 2004, Merck withdrew Vioxx from the market. Thousands of lawsuits ensued across the country. On September 6, 2005, Texas cases were consolidated into this MDL proceeding. There are currently over 1,000 Vioxx cases in these consolidated Texas proceedings; virtually all of them contain an allegation that Merck failed to provide an adequate warning.

2. Preemption

A. The Texas Act

In 2003, the Texas legislature enacted TEX. CIV. PRAC. & REM. CODE ANN. § 82.007, which provides, in part:

> **§ 82.007. Medicines**
>
> (a) In a products liability action alleging that an injury was caused by a failure to provide adequate warnings or information with regard to a pharmaceutical product, there is a rebuttable presumption that the defendant or defendants, including a health care provider, manufacturer, distributor, and prescriber, are not liable with respect to the allegations involving failure to provide adequate warnings or information if:
>
> > (1) the warnings or information that accompanied the product in its distribution were those approved by the United States Food and Drug Administration for a product approved under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. Section 301 et seq.), as amended, or

> Section 351, Public Health Service Act (42 U.S.C. Section 262), as amended; or
>
> * * * *
>
> (b) The claimant may rebut the presumption in Subsection (a) as to each defendant by establishing that:
>
> (1) the defendant, before or after pre-market approval or licensing of the product, withheld from or misrepresented to the United States Food and Drug Administration required information that was material and relevant to the performance of the product and was causally related to the claimant's injury;
>
> * * * *

TEX. CIV. PRAC. & REM. CODE ANN. § 82.007 (hereinafter the "Texas Act"). The Texas Act was one of a number of enactments in 2003 designed to achieve "tort reform" as a result of a perceived lawsuit crisis, particularly involving the medical arena. This statute has yet to be construed by Texas appellate courts.

There is no question but that the FDA approved the general warnings or information provided by Merck with respect to Vioxx. Plaintiffs rely exclusively upon subsection (b)(1) of the Texas Act in order to rebut the Act's presumption that Merck is not liable for failure to provide an adequate warning.

B. Construction of the Texas Act.

In order to determine whether the Texas Act has been preempted, this Court must first construe the various terms contained in the Act.

1. Burden of Proof.

A threshold question confronting this Court concerns the burden of proof under the Texas Act. Section 82.007 states that a claimant may rebut the presumption in the statute by "establishing" that certain required information was withheld. What does "establish" mean? Merck equates "establish" with "prove" and argues that plaintiffs must prove that such information was withheld or misrepresented by a preponderance of the evidence. Plaintiffs argue that the presumption "bursts" merely upon presenting some evidence that information was withheld. Thus, according to plaintiffs, at the conclusion of plaintiffs' case, the Court would rule as a matter of law whether some evidence of withholding or misrepresentation of evidence was presented, and thereafter, the failure to warn question would be presented to the jury. Plaintiffs therefore argue that the court, rather than the jury, decides whether information was withheld.

The Court agrees with Merck. Plaintiffs have the burden to "establish" or prove that required information was withheld from or misrepresented to the FDA by a preponderance of the evidence. This is ordinarily a question for the jury.

2. Required Information

To rebut the presumption, plaintiffs must show that "required information" was withheld or misrepresented. "Required information" means that information which is required to be submitted to the FDA pursuant to federal statute and regulations governing pharmaceutical products.

3. Material Information.

The Texas Act next requires that claimants prove that "material and relevant" information was withheld. Not surprisingly, the parties presented two different definitions of materiality.

- Plaintiffs posit that they must merely show "that the allegedly withheld information, if disclosed, would have a natural tendency to influence, or be capable of influencing, a government function."
- Merck, on the other hand, argues that plaintiffs must show "that the allegedly withheld information, if disclosed, in reasonable probability would have led to a different regulatory outcome such as refusal to approve Vioxx for marketing or requiring a label change."

Plaintiffs proposed definition is erroneous for several reasons. First, the definition would effectively make any relevant information sufficient to eliminate the presumption. Under the plaintiffs definition, virtually any information would qualify. Since the Texas Act was promulgated in an environment of tort reform, the legislature surely meant that the burden on plaintiffs be more than merely finding "some information" that "might" be capable of influencing the FDA. This Court may consider the circumstances surrounding a statute and the goals sought to be achieved by the legislature in construing a statute. *See Lexington Ins. Co. v. Strayhorn*, 209 S.W.3d 615 (Tex. 2005).

Second, the Texas Act requires that the withheld information be "causally related" to the plaintiff's injury. Unless withheld information would have resulted in some definite change by the FDA, either non-approval of the

drug, or a labeling change, such with withheld information could not be causally related to a plaintiff's injury.

Thus, plaintiffs must prove by a preponderance of the evidence that required information was withheld from or misrepresented to the FDA, such that the allegedly withheld or misrepresented information, if disclosed or not misrepresented, would have led to a different regulatory outcome such as refusal to approve Vioxx for marketing or requiring a label change.

4. Relevant information

The allegedly withheld or misrepresented information must relate to the same injury complained of by plaintiff.

C. Preemption of the Texas Act

The starting point of any preemption analysis concerning the Texas Act is *Buckman Co. v. Plaintiffs' Legal Committee,* 531 U.S. 341 (2001), where the Supreme Court held that state law "fraud on the FDA" claims are preempted by the Food, Drug and Cosmetic Act, 21 U.S.C. § 301, *et seq.* ("FDCA"). There, Buckman was a consulting company that assisted a manufacturer to obtain FDA approval for certain medical devices. Plaintiffs were consumers of these devices, who claimed personal injuries; plaintiffs sued Buckman alleging that Buckman made fraudulent representations to the FDA. Plaintiffs claimed that such misrepresentations were a "but for" cause of injuries: had the representations not been made, the FDA would not have approved the device, and plaintiffs would not have been injured. The Supreme Court held that such claims are preempted by the FDCA. The Court reasoned that it is the FDA's exclusive responsibility to "police fraud consistently with the Administration's judgment and objectives." *Id.*

at 350. The Court observed that the FDA is empowered to investigate fraud and that citizens may report wrongdoing and petition the agency to take action. *Id.* at 349. Moreover, "fraud-on-the FDA claims would also cause applicants to fear that their disclosures to the FDA, although deemed appropriate by the Administration, will later be judged insufficient in state court" resulting in a "deluge" of needless information on the FDA, potentially burdening the agency and delaying release of new products. *Id.* at 351.

Since *Buckman,* several courts have considered statutes similar to the Texas Act. In *Garcia v. Wyeth-Ayerst Laboratories,* 385 F.3d 961 (6th Cir. 2004), the Sixth Circuit considered a Michigan law that immunizes a drug manufacturer from products liability suits if the drug was approved by the FDA unless the manufacturer intentionally withheld or misrepresented required information.[1] The court held the Michigan law was preempted

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[1] The statute provides, in relevant part: "(5) In a product liability action against a manufacturer or a seller, a product that is a drug is not defective or unreasonably dangerous, and the manufacturer or seller is not liable, if the drug was approved for safety and efficacy by the United States food and drug administration, and the drug and its labeling were in compliance with the United States food and drug administration's approval at the time the drug left the control of the manufacturer or seller. . . . This subsection does not apply if the defendant at any time before the event that allegedly caused the injury does any of the following:

> (a) Intentionally withholds from or misrepresents to the United States food and drug administration information concerning the drug that is required to be submitted under the federal food, drug, and cosmetic act. . . , and the drug would have not been approved, or the United States food and drug administration would have withdrawn approval for the drug if the information were accurately submitted.

MICH. COMP. LAWS § 600.2946(5).

to the extent that it permitted a state court to determine whether a drug manufacturer committed fraud on the FDA. *Id.* at 966. However, such "inter-branch-meddling concerns that animated *Buckman*" do not arise when the "FDA *itself* determines that a fraud has been committed on the agency during the regulatory-approval process." *Id.* (emphasis in original) Thus, the court held that a plaintiff could only invoke the "fraud on the FDA" exception to the Michigan statute if the FDA itself determines that it was defrauded. Other courts have reached similar conclusions. *See, e.g., Henderson v. Merck & Co.*, 2005 WL 2600220 (E.D. Pa., Oct. 11, 2005); *Kobar v. Novartis Corp.*, 378 F. Supp. 2d 1166, 1172-74 (D. Ariz. 2005).

Plaintiffs, however, rely on *Desiano v. Warner-Lambert & Co.*, 467 F.3d 85 (2d Cir. 2006), which reached a different conclusion and suggested three reasons why the *Garcia* analysis is flawed. First, plaintiffs correctly note that there is a presumption against preemption. While such a presumption exists, *see Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 518 (1992), the Supreme Court in *Buckman* expressly held that no such presumption against preemption existed in that case. "The relationship between a federal agency and the entity it regulates is inherently federal in character because the relationship originates from, is governed by, and terminates according to federal law." 531 U.S. at 347. Because, in that case, the medical device manufacturer's dealings with the FDA were prompted by federal law, "no presumption against preemption obtains in this case." *Id.* The same analysis must apply with no less force to drug manufacturers. Indeed, the State of Texas, by enacting the Texas Act, has placed the relationship between drug manufacturer and FDA in issue.

Second, plaintiffs argue that *Buckman* is inapplicable since it involved a non-traditional suit based entirely on a fraud on the FDA theory, whereas these suits allege traditional products liability theories. This is a distinction without a difference. Under the Texas Act, in order to pursue a failure to warn case, plaintiffs must prove that required and material information was withheld from the FDA. Whether it is an element of plaintiffs' cause of action, or a way to defeat an affirmative defense, the proof is the same. All of the federalism concerns expressed in *Buckman* still apply. The requisite showing under the Texas Act is analogous to and sufficiently equivalent to plaintiffs' asserting a claim of fraud on the FDA that the claim is preempted under *Buckman*.

Finally, plaintiffs argue that the proof required under the Texas Act is different from a "fraud on the FDA" complaint. Plaintiffs argue that mere inadvertent withholding of information is sufficient to puncture the rebuttable presumption of the Texas Act[2], whereas intentional fraud was at issue in *Buckman*, and, indeed, part of the statute in Michigan. This Court is not persuaded by this argument. The logic of *Buckman* was that the FDA promulgates detailed data submission requirements and is fully empowered to investigate wrongful withholding by manufacturers. 531 U.S. at 1017. If anything, the argument that *Buckman* involved a claim with an element of scienter, whereas the Texas Act requires only inadvertent withholding undermines plaintiffs' argument. State courts traditionally adjudicate a party's state of

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[2] The Court notes that the Texas Act uses the word "misrepresents" which could imply an element of intent, depending on whether the misrepresentation required is intentional or negligent. However, for purposes of this motion, the Court will assume no scienter is required since the statute disjunctively includes "withheld from" as sufficient to eliminate the statutory rebuttable presumption.

mind, *e.g.*, whether fraud occurs. Indeed, a state court is probably better suited than a federal agency to determine whether an intentional misrepresentation occurred as opposed to an inadvertent omission. The key issue for purpose of presumption analysis is not whether information was intentionally withheld, but whether the federal regulation is so pervasive as to leave no room for state regulation. Given the extent of federal regulation, and the extent to which the FDA is empowered to investigate and regulate drug manufacturers who fail to provide required information, permitting a Texas jury or judge to make the same inquiry would impinge on a uniquely federal issue.

All of the concerns raised by the Supreme Court in *Buckman* would manifest themselves if the motion for summary judgment were denied. *Buckman* noted that manufacturers might "deluge" the FDA with information it neither needed nor wanted in order to defend state tort claims. 531 U.S. at 351. This could potentially impede the regulatory process. The *Buckman* concern of deluging the FDA could well come true if manufacturers were forced to make data submissions defensively in order to ensure that the presumption of the Texas Act remained in place.

There is no question but that the FDA has not made a determination that material and relevant information was either withheld or misrepresented concerning Vioxx.

C. Severability

Plaintiffs argue that if subsection (b)(1) is preempted, then the entirety of section 82.007 must fall, leaving no presumption that Merck's is not liable with respect to the allegations involving failure to provide adequate warnings. This argument fails. First, plaintiffs can still avail themselves of (b)(1) if the FDA determines that required

information was withheld. The issue is who makes the determination—the FDA or a Texas court or jury.

Second, the Texas Act is severable. Texas law currently provides that:

> (c) in a statute that does not contain a provision for severability or nonseverability, if any provision of the statute or its application to any person or circumstance is held invalid, the invalidity does not affect other provisions or applications of the statute that can be given effect without the invalid provision or application, and to this end the provisions of the statute are severable.

TEX. GOV'T. CODE § 311.032(c). Unless the legislature provides for nonseverability, the Government Code provides that the statute is severable. Even if subsection (b)(1) is invalid, the remaining statute can be given effect.

Finally, in passing the Texas Act, the legislature expressly considered the possibility that the law would not survive a *Buckman* analysis.[3] Yet, notwithstanding this forewarning, the legislature did not insert a nonseverability provision into § 82.007.

D. Conclusion on Preemption

For the forgoing reasons, Merck's motion for partial summary judgment is granted and subsection (13)(1) of TEX. CIV. PRAC. & REM. CODE ANN. § 82.007 is preempted to the extent that someone other than the FDA is being asked to make the determination. Plaintiffs cannot

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[3] For example, Baylor Law School Dean Bradley Tobin testified in Senate committee hearings that § 82.007 could very well be challenged on *Buckman* grounds. Hearings on Tex. H.B. 4 Before Senate State Affairs Comm., 78th Leg., R.S. at 23-24 (May 5, 2003).

rely on subsection (b)(1) unless and until the FDA makes the required findings under (b)(1).

3. Merck's Alternative Motion

Merck argued alternatively that even if the Texas Act is not preempted, a no evidence motion for summary judgment should nevertheless be granted. Merck argues that plaintiffs do not have sufficient evidence to rebut the presumption.

In response, plaintiffs submit the affidavits of various experts. However, because of this Court's ruling on preemption, it is not necessary to rule on Merck's alternative motion.

Plaintiff's motion to strike Merck's Summary Judgment evidence is Denied.

Plaintiff's claim of failure to warn is hereby severed from this Master Docket and will henceforth be under cause number 2005-59499A and in the original trial court as Cause No. 2005-58543A. The pleadings in this severed cause shall consist of plaintiff's petition(s), defendants' answer(s), Merck's motion for partial summary judgment and all responses, replies, rebuttals and other briefs and memoranda concerning the motion for summary judgment.

This is a final order and is appealable.

It is further ordered that any appeal from this Order be expedited pursuant to Tex. R. Jud. Admin. 13.9(c) as this order is made in MDL pretrial proceedings.

Signed April 19, 2007.

/s/ HON. RANDY WILSON
Hon. Randy Wilson

UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION

Case: 01-73249
Judge: Gerald E. Rosen
Magistrate Judge Morgan

CONNIE ARMSTRONG, LAURANANE BRADLEY and RAYMOND BRADLEY, GLENN CHANDLER, BILLIE FLYNT, SHELLY GROTENHUIS, JUDY HEARN, COLLEEN HERNDON and MICHAEL W. HERNDON, MICHAEL KANAKRY and MARY ANN KANAKRY, JULIA MARTIN and ROYAL M. MARTIN, JANICE L. KIMMEL, Personal Representative of the Estate of Thea Martz, Deceased, MONA PRZYTULSKI, DAVID A. RICE, Personal Representative of the Estate of Robert Rice, Deceased, ANITA SCHULTZ and RICHARD P. SCHULTZ, JAMES K. SOUKUP, Personal Representative of the Estate of Barbara Soukup, Deceased, JENNIFER ST. PIERRE, Personal Representative of the Estate of Raymond St. Pierre, Deceased, DONALD WAUN and JEANENE WAUN,

Plaintiffs,

—v.—

WARNER-LAMBERT COMPANY AND PARKE-DAVIS, a division of Warner-Lambert Company, Delaware Corporations, Jointly and Severally,

Defendants.

J. Douglas Peters (P25686)
CHARFOOS & CHRISTENSEN, P.C.
Attorneys for Plaintiffs
5510 Woodward Avenue
Detroit, MI 48202
(313) 875-8080

Complaint and Demand For Jury Trial

NOW COME the plaintiffs, by and through their attorneys, CHARFOOS & CHRISTENSEN, P.C., and for their complaint against the defendants, state as follows:

1. That the plaintiff, Connie Armstrong, is a resident of the City of Flint, County of Genesse, State of Michigan.

2. That the plaintiffs, Lauranane Bradley and Raymond Bradley, are residents of the City of Ypsilanti, County of Washenaw, State of Michigan.

3. That the plaintiff, Glenn Chandler, is a resident of the City Ownedale, County of Huron, State of Michigan.

4. That the plaintiff, Billie Flynt, is a resident of the City of Flint, County of Genesee, State of Michigan.

5. That the plaintiff, Shelly Grotenhuis, is a resident of the City of Holland, County of Allegan, State of Michigan.

6. That the plaintiff, Judy Hearn, is a resident of the City of Detroit, County of Wayne, State of Michigan.

7. That the plaintiffs, Colleen Herndon and Michael W. Herndon, are residents of the City of Canton, County of Wayne, State of Michigan.

8. That the plaintiffs, Michael Kanarky and Mary Ann Kanakry, are residents of the City of St. Clair Shores, County of Macomb, State of Michigan.

9. That the plaintiffs, Julia Martin and Royal M. Martin, are residents of the City of Shelbyville, State of Tennessee.

10. That the plaintiff, Janice L. Kimmel, Personal Representative of the Estate of Thea Martz, Deceased, is a resident of the City of Midland, County of Midland, State of Michigan and that plaintiff's decedent, Thea Martz, at all times pertinent hereto, was a resident of the City of Midland, County of Midland, State of Michigan.

11. That the plaintiff, Mona Przytulski, is a resident of the Township of East China, County of St. Clair, State of Michigan.

12. That the plaintiff, David A. Rice, Personal Representative of the Estate of Robert Rice, Deceased, is a resident of the City of Battle Creek, County of Calhoun, State of Michigan and that at all times pertinent hereto, plaintiff's decedent, Robert Rice, was a resident of the Rochester Hills, County of Oakland, State of Michigan.

13. That the plaintiffs, Anita Schultz and Richard P. Schultz, are residents of the City Hudson, County of Lenawee, State of Michigan.

14. That the plaintiff, James K. Soukup, Personal Representative of the Estate of Barbara Soukup, Deceased, is a resident of the City of Mesick, County of Wexford, State of Michigan and that at all times relevant hereto, plaintiff's decedent, Barbara Soukup, was a resident of the City of Cadillac, County of Wexford, State of Michigan.

15. That the plaintiff, Jennifer St. Pierre, Personal Representative of the Estate of Raymond St. Pierre, Deceased, is a resident of the City of Fenton, County of Genesee, State of Michigan and that at all times relevant hereto, plaintiff's decedent, Raymond St. Pierre, was a resident of the City of Grand Blanc, County of Genesee, State of Michigan.

16. That the plaintiffs, Donald Waun and Jeanene Waun, are residents of the City of Warren, County of Macomb, State of Michigan.

17. That defendant, Warner-Lambert Company, is incorporated in the State of Delaware with its principal place of business being Morris Plains, New Jersey.

18. That defendant, Parke-Davis, a division of Warner-Lambert Company, is a Delaware Corporation with its principal place of business in Morris Plains, New Jersey, and thus, there is diversity between the plaintiffs and defendants.

19. That the amount in controversy exceeds the jurisdictional amount of Seventy-Five Thousand ($75,000.00) Dollars.

20. That plaintiffs and plaintiffs' decedents were consumers were prescribed who ingested the drug Rezulin, chemically known as Troglitazone.

21. That the defendants, Warner-Lambert Company, and Parke-Davis, a division of Warner-Lambert Company, are either manufacturers themselves or by use of others did manufacture, create, design, test, label, supply, promote, advertise, warn, and otherwise distribute in the United States the product Rezulin, chemically known as Troglitazone.

22. That defendants are manufacturers of Rezulin, chemically known as Troglitazone, and had a duty to plaintiffs and plaintiffs' decedents to warn of the dangerous medical side effects of said drug; however, the defendants did the following negligent, fraudulent, misrepresentation and product defect related acts (breach of warranty; breach of fitness for intended purpose):

A. Failed to use due care in designing and manufacturing Rezulin so as to avoid risks to individuals when Rezulin was being used for treatment of Type II Diabetes.

B. Failed to accompany their product with proper and timely warnings regarding all possible adverse side effects associated with the use of Rezulin and the comparative severity and duration of such adverse effects, and/or the warnings given did not accurately reflect the symptoms, scope or severity of the side effects.

C. Failed to conduct adequate pre-clinical and clinical testing and post-marketing surveillance to determine the safety of Rezulin.

D. Failed to provide adequate training to medical care providers for appropriate use of Rezulin.

E. Failed to warn plaintiffs and plaintiffs' decedents prior to actively encouraging the sale of Rezulin, either directly or indirectly, orally or in writing, about the following:

i. The need for comprehensive regular medical monitoring to insure early discovery of potentially fatal liver and/or cardiac side effects;

ii. The possibility of death as the result of liver failure or heart failure.

F. Engaged in deceptive and misleading practices, including withholding information from consumers, physicians and the FDA about the adverse event reports confirming liver and heart damage and the deaths associated with the drug.

G. Continued to aggressively publicize Rezulin as having side effects comparable to a placebo even though the defendants' company's own clinical trial data which had been submitted to the FDA as part of a new drug application indicated that patients in clinical trials develop liver problems four times as often as the controls who had received a placebo.

H. Withheld information from consumers, their doctors and the FDA to insure the continued success of what had become a billion dollar blockbuster drug. Sales of Rezulin to approximately two million diabetics generated revenues estimated at over $1.8 billion dollars.

23. That the defendants' product was unsafe for its intended use and was defective by reason of design, distribution, manufacturing, promotion, testing, and lack of adequate warnings, knowingly concealed material facts about the safety and efficacy of Rezulin from the FDA, which would have prevented its approval and/or resulted in its earlier removal from the market.

WHEREFORE, plaintiffs, pray for relief as follows:

1. For general damages for each plaintiff in a sum in excess of the jurisdictional minimum of this court.

2. Medical, incidental, hospital, and service expenses according to proof.
3. Loss of earnings and earning capacity.
4. Pre-judgment and post-judgment interest as provided by law.
5. Full refund of purchase costs incurred by plaintiffs and plaintiffs' decedents for Rezulin.
6. Compensatory damages in excess of the jurisdictional minimum of the court, according to proof.
7. Consequential damages in excess of the jurisdictional minimum of the court, according to proof.
8. Exemplary/punitive damages.
9. Attorney fees, expenses, and costs of this action.
10. Such further relief as this court deems necessary, just and proper.

CHARFOOS & CHRISTENSEN, P.C.

By: /s/ J. DOUGLAS PETERS
J. DOUGLAS PETERS (P25686)
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August 20, 2001

UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION

Case: 01-73249
Judge: Gerald E. Rosen
Magistrate Judge Morgan

CONNIE ARMSTRONG, LAURANANE BRADLEY and RAYMOND BRADLEY, GLENN CHANDLER, BILLIE FLYNT, SHELLY GROTENHUIS, JUDY HEARN, COLLEEN HERNDON and MICHAEL W. HERNDON, MICHAEL KANAKRY and MARY ANN KANAKRY, JULIA MARTIN and ROYAL M. MARTIN, JANICE L. KIMMEL, Personal Representative of the Estate of Thea Martz, Deceased, MONA PRZYTULSKI, DAVID A. RICE, Personal Representative of the Estate of Robert Rice, Deceased, ANITA SCHULTZ and RICHARD P. SCHULTZ, JAMES K. SOUKUP, Personal Representative of the Estate of Barbara Soukup, Deceased, JENNIFER ST. PIERRE, Personal Representative of the Estate of Raymond St. Pierre, Deceased, DONALD WAUN and JEANENE WAUN,

Plaintiffs,

—v.—

WARNER-LAMBERT COMPANY AND PARKE-DAVIS, a division of Warner-Lambert Company, Delaware Corporations, Jointly and Severally,

Defendants.

J. Douglas Peters (P25686)
CHARFOOS & CHRISTENSEN, P.C.
Attorneys for Plaintiff
5510 Woodward Avenue
Detroit, MI 48202
(313) 875-8080

DEMAND FOR JURY TRIAL

NOW COME the plaintiffs, by and through their attorneys, CHARFOOS & CHRISTENSEN, P.C., and hereby demand a trial by jury of the within cause.

CHARFOOS & CHRISTENSEN, P.C.

By: /s/ J. DOUGLAS PETERS
J. DOUGLAS PETERS (P25686)
Attorneys for Plaintiffs
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August 20, 2001

UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION

Case No. 00-71806
Judge: Gerald E. Rosen
Magistrate Judge Capel

KIMBERLY KENT, Personal Representative of the Estate of Virginia Kent, Deceased, Emmett Kent on behalf of themselves and all other similar situated,

Plaintiffs,

—v.—

WARNER-LAMBERT COMPANY AND PARKE-DAVIS, a division of Warner-Lambert Company, Delaware Corporations, Jointly and Severally,

Defendants.

J. Douglas Peters (P25686)
CHARFOOS & CHRISTENSEN, P.C.
Attorneys for Plaintiffs
5510 Woodward Avenue
Detroit, MI 48202
(313) 875-8080

CLASS ACTION COMPLAINT AND DEMAND FOR JURY-TRIAL

NOW COME the plaintiffs, Kimberly Kent, Personal Representative of the Estate of Virginia Kent, Deceased, and Emmett Kent, individually and as class representatives, by and through their attorneys, CHARFOOS & CHIRSTENSEN, P.C., and for their complaint against the defendants, states and follows:

1. That the plaintiffs, Kimberly Kent, Personal Representative of the Estate of Virginia Kent, Deceased, and Emmett Kent are residents of the City of Detroit, County of Wayne, State of Michigan, United States of America.

2. That defendant, Warner-Lambert Company, is incorporated in the State of Delaware with its principal place of business being Morris Plains, New Jersey.

3. That defendant, Parke-Davis, a division of Warner-Lambert Company, is a Delaware Corporation with its principal place of business in Morris Plains, New Jersey, and thus, there is diversity between the plaintiffs and defendants.

4. That the amount in controversy exceeds the jurisdictional amount of Seventy-Five Thousand ($75,000.00) Dollars.

5. That plaintiff's decedent was a consumer and brings this action pursuant to F.R.Civ.P. 23 on behalf of all similarly situated persons in the United States who were prescribed and who ingested the drug Rezulin, chemically known as Troglitazone.

6. That the defendants, Warner-Lambert Company, and Parke-Davis, a division of Warner-Lambert Company, are either manufacturers themselves or by use of others did manufacture, create, design, test, label, dis-

tribute, supply, promote, advertise, warn, and otherwise distribute in the United States the product Rezulin, chemically known as Troglitazone.

7. That defendants are manufacturers of Rezulin, chemically known as Troglitazone, and had a duty to plaintiff's decedent, Virginia Kent, and other members of the class who are/were similarly situated to warn of the dangerous medical side effects of said drug, however, the defendants did the following negligent, fraudulent, misrepresentation and product defect related acts (breach of warranty; breach of fitness for intended purpose):

A. Failed to use due care in designing and manufacturing Rezulin so as to avoid risks to individuals when Rezulin was being used for treatment of Type II Diabetes.

B. Failed to accompany their product with proper and timely warnings regarding all possible adverse side effects associated with the use of Rezulin and the comparative severity and duration of such adverse effects, and/or the warnings given did not accurately reflect the symptoms, scope or severity of the side effects.

C. Failed to conduct adequate pre-clinical and clinical testing and post-marketing surveillance to determine the safety of Rezulin.

D. Failed to provide adequate training to medical care providers for appropriate use of Rezulin.

E. Failed to warn plaintiff's decedent and all others similarly situated prior to actively encouraging the sale of Rezulin, either directly or

indirectly, orally or in writing, about the following:

i. The need for comprehensive regular medical monitoring to insure early discovery of potentially fatal liver and/or cardiac side effects;

ii. The possibility of death as the result of liver failure or heart failure.

8. That the defendants' product was unsafe for its intended use and was defective by reason of design, distribution, manufacturing, promotion, testing, and lack of adequate warnings, knowingly concealed material facts about the safety and efficacy of Rezulin from the FDA, which would have prevented its approval and/or resulted in its earlier removal from the market.

A. Engaged in deceptive and misleading practices, including withholding information from consumers, physicians and the FDA about the adverse event reports confirming liver and heart damage and the deaths associated with the drug.

B. Continued to aggressively publicize Rezulin as having side effects comparable to a placebo even though the defendants' company's own clinical trial data which had been submitted to the FDA as part of a new drug application indicated that patients in clinical trials develop liver problems four times as often as the controls who had received a placebo.

C. Withheld information from consumers, their doctors and the FDA to insure the continued success of what had become a billion dollar

blockbuster drug. Sales of Rezulin to approximately two million diabetics generated revenues estimated at over S1.8 billion dollars.

CLASS ACTION INJUNCTIVE EQUITABLE RELIEF

I. Medical Monitoring.

9. Plaintiffs incorporate by reference all other paragraphs of this complaint as if fully set forth herein and further allege as follows on behalf of themselves and all other similarly situated.

10. As a direct and proximate result of the defendants' acts, omissions and conduct as set forth above, plaintiff's decedent and each class member have been exposed to a hazardous substance and as a result suffer a significantly increased risk of serious injury or latent disease including liver and heart damage. This increased risk makes periodic diagnostic and medical examinations reasonable and necessary.

11. Easily administered, cost-effective monitoring and testing procedures exist which make the early detection and treatment of such injuries or disease possible and beneficial. For example, administration of a readily available, non-invasive test to diagnose the presence of liver or heart damage.

12. The recommended testing procedures will be subject to expert testimony at the time of trial. Appropriate testing regimes, based upon claimant information received from class members, will likely include non-invasive readily administrable initial tests and procedures, tailored to the individual claimant: e.g. echocardiograms, blood tests and liver function studies.

13. Many individuals at risk for liver and/or heart damage cannot afford to get appropriate testing and/or have not been advised and do not otherwise know of a need to undergo testing. Class members also need to be advised of the availability of non-invasive testing as a diagnostic tool and treatment which will prevent even graver injury.

14. The increased susceptibility to injuries and irreparable threat to the health of class members resulting from their exposure to Rezulin can only be mitigated or addressed by the creation of a comprehensive medical monitoring program:

A. Notifying consumers who used Rezulin of the potential harm from said drug;

B. Funding from further studies of the long term effects on users for Rezulin;

C. Funding research and possible cures for the detrimental effects of using Rezulin;

D. Gathering and forwarding to treating physicians information related to the diagnosis and treatment of injuries which may result from using Rezulin and;

E. Aiding in the early diagnosis and treatment of resulting injuries through ongoing testing and monitoring of Rezulin users.

15. Rezulin users without present serious injury have no adequate remedy at law in that monetary damages do not compensate for the continuing nature of the harm to them, and a monitoring program which notifies them of possible injury and aids in their treatment can prevent greater harms which may not occur immediately and which may be preventable if proper research is con-

ducted and the health risks are diagnosed and treated before they occur or become worse.

16. Plaintiff's decedent and class members' susceptibility to liver and heart damage is the significant result of their use of Rezulin. Early detection and diagnosis of these diseases is clinically invaluable since it can prevent or significantly delay resulting discomfort, disease and/or death.

17. Without a court-approved medical monitoring program, Rezulin users will not receive prompt medical care that could detect problems and prolong their productive lives, increase prospects for improvement minimize disability.

II. Updated Patient Warnings and Emergency Notice.

18. Plaintiffs incorporate by reference all other paragraphs of this complaint as if fully set forth herein and further allege as follows on behalf of themselves and all other similarly situated.

19. Defendants have a continuing duty to warn the class and the public of all potential risks and dangers of which they become or should become aware. There are studies underway regarding these risks and dangers. As a proximate result of the defendants' conduct described herein, plaintiff's decedent, on behalf of herself and all others similarly situated, are entitled to damages and/or equitable relief in the form of revised warnings, or equivalent remedial and corrective action, to accurately reflect the known adverse side effects of Rezulin, including liver and/or heart damage, even though Rezulin has been withdrawn from the market.

20. Defendants should be required to provide continuously updated product warnings to individuals who use and/or have previously used Rezulin for the treatment of Diabetes to provide them with timely information concerning effective testing and treatment options for those suffering from, or at risk for, liver and/or heart damage or other injury caused by Rezulin.

WHEREFORE, plaintiffs, pray for relief as follows:

A. Class-wide relief.

1. That this action and the causes of action asserted be certified as a class action on behalf of the proposed class of consumers who have ingested Rezulin and that the named plaintiffs be designated as representative of the class and that the named counsel be designated class counsel.

2. Creation of a comprehensive, court-supervised medical monitoring which will include:

a. Insure early diagnosis and treatment of resulting liver and heart injuries through ongoing testing and monitoring of Rezulin users;

b. Notify consumers who use or used Rezulin of the potential liver and heart damage from Rezulin;

c. Fund further studies of the long term liver and heart effects on Rezulin users;

d. Fund research and possible cures for the detrimental liver and heart effects of using Rezulin;

e. Gather and forward to treating physicians information related to the diagnosis and treatment of liver and heart damage which may result from using Rezulin; and

f. Provide class members with revised drug warnings and emergency notice.

3. The designation of any additional classes and subclasses and the appointment of any additional class representatives that the court may deem necessary or appropriate in connection with its class certification determinations including, but not limited to, the designation of classes, subclasses and/or class representatives with respect to each of the named defendants.

4. Award general, special and punitive/exemplary damages as well as attorney fees, expenses and costs of this action, including the costs of notices to the class.

B. Individual relief for individual plaintiffs.

1. For general damages for plaintiff and each class member in a sum in excess of the jurisdictional minimum of this court.

2. Medical, incidental, hospital, and service expenses according to proof.

3. Loss of earnings and earning capacity.

4. Pre-judgment and post-judgment interest as provided by law.
5. Full refund of purchase costs incurred by plaintiff's decedent and the members of the class for Rezulin.
6. Compensatory damages in excess of the jurisdictional minimum of the court, according to proof.
7. Consequential damages in excess of the jurisdictional minimum of the court, according to proof.
8. Exemplary/punitive damages.
9. Attorney fees, expenses, and costs of this action.
10. Such further relief as this court deems necessary, just and proper.

CHARFOOS & CHRISTENSEN, P.C.

By: /s/ J. DOUGLAS PETERS
J. DOUGLAS PETERS (P25686)
Attorneys for Plaintiff
5510 Woodward Avenue
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(313) 875-8080

Dated: April 17, 2000

UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION

Case No. 03-70501
Judge: Gerald E. Rosen
Magistrate Judge R. Steven Whalen

LINDA SHERMAN and STANLEY SHERMAN,

Plaintiffs,

—v.—

WARNER-LAMBERT COMPANY and PARKE-DAVIS, a division of Warner-Lambert Company, Delaware Corporations, Jointly and Severally,

Defendants.

J. Douglas Peters (P25686)
CHARFOOS & CHRISTENSEN, P.C.
Attorneys for Plaintiffs
5510 Woodward Avenue
Detroit, MI 48202
(313) 875-8080

COMPLAINT AND DEMAND FOR JURY TRIAL

NOW COME the plaintiffs, by and through their attorneys, CHARFOOS & CHRISTENSEN, P.C., and for their complaint against the defendants, state as follows:

1. That the plaintiffs, LINDA SHERMAN and STANLEY SHERMAN, are residents of the City of Onsted, County of Lenawee, State of Michigan.

2. That defendant, Warner-Lambert Company, is incorporated in the State of Delaware with its principal place of business being Morris Plains, New Jersey.

3. That defendant, Parke-Davis, a division of Warner-Lambert Company, is a Delaware Corporation with its principal place of business in Morris Plains, New Jersey, and thus, there is diversity between the plaintiffs and defendants.

4. That the amount in controversy exceeds the jurisdictional amount of Seventy-Five Thousand ($75,000.00) Dollars.

5. That plaintiffs were consumers who were prescribed and who ingested the drug Rezulin, chemically known as Troglitazone.

6. That the defendants, Warner-Lambert Company, and Parke-Davis, a division of Warner-Lambert Company, are either manufacturers themselves or by use of others did manufacture, create, design, test, label, supply, promote, advertise, warn, and otherwise distribute in the United States the product Rezulin, chemically known as Troglitazone.

7. That defendants are manufacturers of Rezulin, chemically known as Troglitazone, and had a duty to plaintiffs and plaintiffs' decedents to warn of the dan-

gerous medical side effects of said drug; however, the defendants did the following negligent, fraudulent, misrepresentation and product defect related acts (breach of warranty; breach of fitness for intended purpose):

A. Failed to use due care in designing and manufacturing Rezulin so as to avoid risks to individuals when Rezulin was being used for treatment of Type II Diabetes.

B. Failed to accompany their product with proper and timely warnings regarding all possible adverse side effects associated with the use of Rezulin and the comparative severity and duration of such adverse effects, and/or the warnings given did not accurately reflect the symptoms, scope or severity of the side effects.

C. Failed to conduct adequate pre-clinical and clinical testing and post-marketing surveillance to determine the safety of Rezulin.

D. Failed to provide adequate training to medical care providers for appropriate use of Rezulin.

E. Failed to warn plaintiffs and plaintiffs' decedents prior to actively encouraging the sale of Rezulin, either directly or indirectly, orally or in writing, about the following:

   i. The need for comprehensive regular medical monitoring to insure early discovery of potentially fatal liver and/or cardiac side effects;

   ii. The possibility of death as the result of liver failure or heart failure.

F. Engaged in deceptive and misleading practices, including withholding information from con-

sumers, physicians and the FDA about the adverse event reports confirming liver and heart damage and the deaths associated with the drug.

G. Continued to aggressively publicize Rezulin as having side effects comparable to a placebo even though the defendants' company's own clinical trial data which had been submitted to the FDA as part of a new drug application indicated that patients in clinical trials develop liver problems four times as often as the controls who had received a placebo.

H. Withheld information from consumers, their doctors and the FDA to insure the continued success of what had become a billion dollar blockbuster drug. Sales of Rezulin to approximately two million diabetics generated revenues estimated at over $1.8 billion dollars.

8. That the defendants' product was unsafe for its intended use and was defective by reason of design, distribution, manufacturing, promotion, testing, and lack of adequate warnings, knowingly concealed material facts about the safety and efficacy of Rezulin from the FDA, which would have prevented its approval and/or resulted in its earlier removal from the market.

WHEREFORE, plaintiffs, pray for relief as follows:

1. For general damages for plaintiffs in a sum in excess of the jurisdictional minimum of this court.

2. Medical, incidental, hospital, and service expenses according to proof.

3. Loss of earnings and earning capacity.

4. Pre-judgment and post-judgment interest as provided by law.
5. Full refund of purchase costs incurred by plaintiffs and plaintiffs' decedents for Rezulin.
6. Compensatory damages in excess of the jurisdictional minimum of the court, according to proof.
7. Consequential damages in excess of the jurisdictional minimum of the court, according to proof.
8. Exemplary/punitive damages.
9. Attorney fees, expenses, and costs of this action.
10. Such further relief as this court deems necessary, just and proper.

CHARFOOS & CHRISTENSEN, P.C.

By: /s/ J. DOUGLAS PETERS
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January 5, 2003

UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION

Case No.
Judge

LINDA SHERMAN and STANLEY SHERMAN,
Plaintiffs,

—v.—

WARNER-LAMBERT COMPANY and PARKE-DAVIS,
a division of Warner-Lambert Company, Delaware
Corporations, Jointly and Severally,
Defendants.

J. Douglas Peters (P25686)
CHARFOOS & CHRISTENSEN, P.C.
Attorneys for Plaintiff
5510 Woodward Avenue
Detroit, MI 48202
(313) 875-8080

DEMAND FOR JURY TRIAL

NOW COME the plaintiffs, by and through their attorneys, CHARFOOS & CHRISTENSEN, P.C., and hereby demand a trial by jury of the within cause.

CHARFOOS & CHRISTENSEN, P.C.

By: /s/ J. DOUGLAS PETERS
J. DOUGLAS PETERS (P25686)
Attorneys for Plaintiffs
5510 Woodward Avenue
Detroit, MI 48202
(313) 875-8080

January 5, 2003